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TRADITIONAL MEDICINE AND DRUG DEVELOPMENT: INDIA'S GOLDEN ROSE

Prof. Dr. Rupam Jagota¹ & Sandeep Kr. Passi²

ABSTARCT

The authors have discussed in detail the above-mentioned topic in five parts. In the first Part the authors have discussed the brief outlook for the existence of Intellectual Property Rights in the pharmaceutical sector and drug patents. Further how pharmaceutical products are protected by utilizing Intellectual Property Rights. In the second part the authors focus his intention to describe the Traditional Knowledge and how the indigenous communities are transferring from generation to generation and is relevant for various treatments. It is imperative to protect this traditional knowledge as it is under serious threat today from the callous neglect visible in various policies. In the third part the authors have given a detailed outline about the Traditional Medicines and how it is the golden rose of India and thus need protection for its development. These various medicinal plants are used for pharmacological targets including cancer, AIDS/HIV, Malaria, and Pain. Opium and Turmeric are plant based and thus used for various other treatments also. In the fourth part the authors present the Indian Traditional Medicine System and its worth as India is the oldest as well as largest tradition of system of medicines. The Indian Traditional Medicine system includes Ayurveda, Sidha, Unani, Homoeopathy, Yoga and Naturopathy. The law also define manufacturing of Ayurveda, Sidha and Unani medicines. In the fifth part the authors give the conclusion and suggestions for the Traditional Medicines and Drug Development.

Keywords: Intellectual Property Rights, Patent, Traditional Knowledge, Traditional Medicines, Drug Manufacturing.

Introduction

The creation and inventions which are being created or invented and protected through legal rights are known as Intellectual Property Rights. Intellectual Property also plays a vital role in

¹ Head, Department of Laws, GNDU Regional Campus, Ladhewali, Jalandhar, Punjab

² Ph.D. Research Scholar, GNDU Regional Campus, Ladhewali, Jalandhar, Punjab.

the modern economy. Traditional Knowledge includes the indigenous heritage and customary heritage rights and also deals with the indigenous cultural and intellectual property as per the World Intellectual Property Organization (WIPO).³ It enables people to earn many financial benefits from their creation and invention. These rights are divided into following categories:

1. Copyrights and their rights
2. Industrial Property

Examples of Intellectual Property Rights are Patents, Trademarks, Copyrights, etc. IPR is one of the vital rights in the pharmaceutical industry. The object of every pharmaceutical industry is to discover the drugs to treat the medical diseases. Drug is discovered by spending the huge amount of money on the research and development.

In the Pharmaceutical Industry, Intellectual Property Rights helps the industry to protect their drug discovery. At the same time IPR also promote the healthy competition between the pharmaceutical industries which has proven to be beneficial for the economy. Patents protects the discovered drugs and bans the other pharmaceutical corporations from manufacturing and selling the same for the time period of 20 years. Patent medicines mainly includes the alcohol and the drugs like opium.⁴ It is necessary to mention that the patent medicines are trademarked in order to keep the secrecy for the formulas of medicine. In the 10th century the opium poppy was first cultivated in India by the native merchants. IPR allows to take the strict action against the pharmaceutical companies who manufacture or sale the counterfeit drugs. Indian Patent Act, 1970 authorizes the Central Government to issue the compulsory license after the grant of the patents.

Traditional Knowledge

The indigenous and various local communities have contributed in the development of traditional knowledge. This knowledge are developed through local environment and further transmitted from generation to generation for the need based therapy. These knowledge changes with the changing environment. A category of TK includes the knowledge for agriculture, knowledge about bio-diversity, knowledge about ecology, knowledge about medicine, scientific information and technical knowledge.⁵ As now the traditional knowledge is under serious risk and many national and international policies are neglecting the traditional knowledge, so it is essential to protect the same. These traditional knowledge require protection

³ WIPO: “Intellectual Property Needs & Expectation of Traditional Knowledge Holders” *available at* www.latestlaws.com (last visited on July 10 2023).

⁴ Charles Fletcher: The Centaur Company and Proprietary Medicine Revenue Stamps.

⁵ World Intellectual Property Organization Report “Finding Missions on Intellectual Property & Traditional Knowledge” (last visited on July 10 2023).

in order to preserve the traditional practices and promotion of its uses so that the local cannot be burden with higher costs. The most of the local communities use these knowledge for healing in daily life and to overcome their nutrition needs. These knowledge of tradition are mostly used in field like agricultural, botanic, biotechnology, research about genes and pharmaceutical.

A patent entails for granting of the domination to the creator who have applied his acquaintance and the abilities for creating an innovative procedure or product that can be employed in the industrial setting. There are specific clauses in the TRIPS Agreement that only apply to the protection of Traditional Knowledge.

Traditional Medicines: India's Golden Rose

Generally 75 percent of the 120 active chemicals now extracted from higher plants that are currently utilized in medicine exhibit and thus showing a positive correlation between traditional knowledge of their use and their therapeutic use.⁶

- 1. The Neem Patent:** The biological name of Neem patent is *Azadirachta indica*. It is also known as “sarva-roga nivarini” and “curer of all ailments” particularly in India, and known as the “wonder tree” in English, which means that the West has discovered the medicinal usage.⁷

A Florida-based agricultural chemical firm was given a patent for the neem tree. A version that can be stored easily was made using the active component, and later on it was isolated. Both the process for making a stabilized azadirachtin in solution and the solution itself are covered by a patent that belongs to the company. As soon as possible, farms started using this solution as a pesticide.⁸

On the surface, the invention appears to be new and original based on consideration of the patentability laws and adhering to the thought of "products of nature". United States also follows the same perception. According to US patent regulations, the entire process of separating and purifying the material, satisfy the criteria for the innovative and inventive step. According to Section 102 of United States Patent Act, preceding foreign use can only render a U.S. patent ineligible if it is fixed in a tangible, readily accessible from, such as by a description in a printed publication, or in a document related to either the applicant's own foreign patent or the foreign patent of another person.⁹

⁶ Gurdial Singh Nijjar, “*TRIPS and Biodiversity, The Threat and responses*” (A third world view)

⁷ es.scribd.com: Visited on July 10 2023

⁸ Id.

⁹ US Patent Law, s.102

Since centuries, India has used a mythical tree as a bio pesticide and medicinal.¹⁰ As early as 5000 BC, Indian Ayurvedic scriptures described the Neem tree and its healing benefits.¹¹ Patent number 436257 has been revoked by the European patent office (EPO) and has given to the W.R. Grace, the multinational corporation and to the United States of America. Recently, emulsions and solutions based on Neem have been excluded from the 12 US patents.

2. **The Turmeric Patent:** The patent right was approved to heal the wound by administering the turmeric in 1993. This patent right was granted to the University of Mississippi Medical Center by US PTO. Since many years, the turmeric has shown several benefits in India. By drying the tuber, turmeric grows up. Indians are very much aware about its practical usage.¹² After re-examination proceedings in the Court, the patent was cancelled in 1998.¹³
3. **The Basmati Rice Patent:** In Sept. 1997, the US Patent office granted patent to “Rice Tec” for the Basmati rice and Aromatic rice. These rice are mostly grown in the parts of India and Pakistan.¹⁴ Indian Government was actively pursuing the case and the final decision was given on August 14, 2001, where the title was changed from Basmati Rice and Grains to Rice Lines Bas 867, RT 117 and T 121. As per the South Asia Commission on Economic and Social Policy, “Rice Tec’s patent also violated the CBD in not recognizing the sovereign rights of India and Pakistan over Basmati Rice.”

After signing the TRIPS Agreement, India can made the transitional agreements through an amendment to the Patent Act. Second amendment was done in year 2000 and the duration of drug patents was extended and also certain new matters was added and even introduced the compulsory license. Then under the third amendment the product patents were introduced and also the fee structure and procedure was changed for the Indian Pharmaceutical Companies.¹⁵ The TRIPS Agreement was came into effect on January 1, 1995. Drug Patents are categorized into following types:

1. **Process Patent:** It is a type of patent by which the process of manufacture of drug could be patented, but not the discovered drug. Thus the other competitors uses the different

¹⁰ Shiva Vandana, “*Indigenous Knowledge and IPRs Biopiracy 69*” (The Plunder of Nature and Knowledge, South End Press, Boston)

¹¹ About Neem available at <https://www.neem.com> (last visited on July 10 2023)

¹² Walker and Simon “*The TRIPS Agreement, Sustainable Development and the Public Interest 36*”(INCUI Law and Policy)

¹³ Gollin, Michael, “*New Rules for Natural Products 921-922*” (Sep. 1999)

¹⁴ Devraj and Ranjit, “*US Corporate Biopirates Still Staking Claim on Basmati Rice*”, (Common Dreams, New Delhi)

¹⁵ Drug Patents in India, available at <https://vakilsearch.com> (last visited on July 10 2023).

methods to manufacture the discovered drug which ultimately leads to the copies and the generic medications.

2. Product Patent: It is a type of patent where the actual discovered drug got patented in India and thus prevent the other pharmaceutical corporations from manufacturing the discovered drugs. This type of patent ensures that the competitors could not make the same drug and thus the pharmaceutical corporation could gain the monopoly over the shares of market for the drug specialized by them.

But in India, it can be categorized into the Non-Patented Drugs and Patented Drugs only. Non-Patented Drugs means when any pharmaceutical corporation can continue to manufacture and supply the drug to the both export and domestic market. Whereas, the Patented Drug means the Manufacture and Supply of such drugs can be possible by the compulsory license. A compulsory license is granted to the party by the administrative body, so as not to exploit an intervention without any authorization of the patent's holder.¹⁶ The main object behind the issuance of compulsory license is to promote the research and for the development of new drugs and in India it is also subjected to the payment of the reasonable royalty. By the Compulsory license the licensee is allowed to produce the generic copy of the discovered drug and the drug which are available in the local market on low price as compare to that of the competitor on the conditions.¹⁷ These various medicinal plants are used for pharmacological targets including cancer, AIDS/HIV, Malaria, and Pain. Opium and Turmeric are plant based and thus used for various other treatments also. Opium is said to be one of the oldest herbal medicine which is currently used for the analgesic, antidiarrheal and sedative treatments. The Opium and its derivatives are the medications commonly used in acute and chronic pain.

As such in Covid-19 Pandemic, there was the urgent demand for the vaccines and medicines in India. Then the compulsory license of covid vaccines and covid drugs was seemed to be appeared as a bonus for the fulfillment of shortage of supplying the drugs and vaccines. For the faster production of the vaccines in India, the govt. may also force the makers of vaccine to share their intellectual property with other companies. Private sector are more threatened and doesn't want to indulge in the prolonged litigation by other multinational companies. So, Compulsory license are now used by the private sector. On dated 27.05.2021, in a press statement, the NITI Aayog clearly mentioned that there should be no compulsory license for the vaccines and drugs of Covid-19.¹⁸ Many countries like South Africa and India have stated

¹⁶ Pharmaceutical industry and patents in India *available at* www.blog.ipleaders.in (last visited on July 10 2023).

¹⁷ Id.

¹⁸ The Indian Dilemma on Compulsory Licensing of the Covid-19 vaccines *available at* <https://www.mondaq.com> (last visited on July 10 2023).

in the WTO Resolution that whether the patent rights may be suspended not only for the vaccines but also for the medicines and other necessary equipment.

Indian Traditional Medicines System and Its Worth

India medicine system is one of the oldest as well as largest traditions. It covers the aspect of all systems which are invented in India and also which are adopted by India from outside. Traditional Indian schemes of medicine include Ayurveda, Siddha and Unani, homeopathy, yoga and naturopathy. Now these are adopted by Indian culture and traditions. India has having the strong traditional medicinal plant knowledge and are having the high plant biodiversity and thus forming one of the greatest potential in this area. There has been a burst in the area of herbal medicine in the recent decades. It has become common in developing and developed countries due to its natural origin and few side effects.¹⁹ Arya Vaidya Shala, Dabur, Himalaya and Shree Baidyanath are the well-known industries and the annual turnover is of more than 50 crores.

Now, the several problems has emerged by the existing Intellectual Property Laws and the existing frameworks. It also need one of the strong measure for protecting the biopiracy. The biopiracy should be protected at national and international level. Presently, there is no legislation which protects the traditional knowledge in India. Thus, following legal protection has been accorded in India to the traditional knowledge:-

1. The Indian Patent Laws and Amendment Act of 2005, which makes it essential to disclose the origin and country of the biological material used in an invention when applying for a patent and permits the patenting of medicinal compounds.
2. The Indian Biodiversity Act 2002 regarding the benefit sharing and it also follows the guidelines of Convention for Biological Diversity.
3. The central authority named “National Biodiversity Authority” has been established by India to keep an eye on and manage foreign access to Indian biological resources, such as traditional medicine.
4. Creation of the "Traditional Knowledge Digital Library" (TKDL), a database that will establish the prior art to prevent Indian knowledge from being patented. NISCAIR, a CSIR Laboratory, has been given responsibility for this mission.

In the past, vaidyas has been used to treat the patients and the drugs are prepared according to the patients requirements. Now the herbal medicines are manufactured in mechanical units, where the manufactures have come across most of the issues such as accessibility of quality

¹⁹ Indian Traditional Medicines *available at* www.nistads.res.in (last visited on July 10, 2023).

raw materials, authenticity of raw materials, accessibility of standards, appropriate standardization method of individual drugs and dosage forms, and control parameters, etc.

Ayurvedic, Siddha, or Unani drugs are defined in Section 3(a) of the Drugs & Cosmetics Act of 1940. All medications intended for internal or external use for or in the diagnosis, treatment, mitigation, or prevention of disease or disorder in humans or animals and manufactured exclusively in accordance with the formulae described in the authoritative books of Ayurvedic, Siddha, and Unani Tibb systems of medicine, as well as those listed in the First Schedule, are considered Ayurvedic, Siddha, or Unani drugs.²⁰ Chapter IVA of Drugs & Cosmetics Act, 1940 is related to the provisions of Ayurvedic, Siddha or Unani Drug.²¹

Schedule T of Drugs & Cosmetics Act, 1940²² deals with the Ayurvedic, Siddha, or Unani medicines should be manufactured using good practices. It states that the following Good Manufacturing Practices (GMP) are required in Parts I and II:

- (i) The raw materials used to make medications are real, of the required quality, and free of contamination.
- (ii) The production procedure follows the guidelines established to uphold the requirements.
- (iii) Sufficient quality control procedures are implemented.
- (iv) The manufactured medicine that has been made available for purchase is of a respectable caliber.
- (v) In order to fulfill the aforementioned goals, each licensee must develop methods and guidelines for adhering to the required medication manufacturing process. These guidelines should be written down in a manual and maintained on hand for inspection and reference.²³

Vaidyas, Siddhas and Hakeems registered under the IMCC Act, 1970 who prepare their own medicines for distribution to their patients and do not sell such medicines in the market are G.M.P.

Conclusion & Suggestion

The currently prepared regulatory system does not cover all issues as the country is still at the stage of developing a strict formulation. The gaps in the laws based on the traditional knowledge needs to be filled up and new laws should be enforced to become one of the major player and

²⁰ The Drugs and Cosmetics Act, 1940, s. 3(a)

²¹ Substituted by The Act 68 of 1982

²² Substituted vide GSR 560(E) dt. 7-3-2003 w.e.f. 7-3-2003

²³ Good Manufacturing Process *available at* www.fdaharyana.org (last visited on July 10, 2023).

well poised.

There are various suggestions that can be advanced in India to grant the protection to knowledge, innovation and practices of traditional medicines and rights dealing with the Intellectual property. It can be following:

1. Documentation of Traditional Knowledge
2. Registration of patent system
3. Innovation of patent system
4. Sui generic system development

It is generally believed that proper documentation of traditional information can help control biopiracy because once the information is documented, it is easily accessible to patent examiners, thus the prior art of inventions based on such material and information is readily available to them. It is also believed that such documentation will make it easier to find indigenous tribes with whom to share the rewards of such knowledge's commercialization. The creation of an international portal for traditional knowledge could make it easier for patent officials and relevant judicial authorities to access these databases. It can also electronically connect traditional knowledge based on data.
