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Analysis of Patent Applications under Indian Patent Law with a Focus on Ayurveda-Related Inventions

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ABSTRACT

Ayurveda, an ancient system of medicine rooted in India's cultural heritage, has become increasingly relevant in modern times. The traditional knowledge of Ayurveda offers valuable insights and remedies that continue to be applicable today. However, with the rise in the commercialization of traditional knowledge, there is a growing interest in patenting Ayurveda-related inventions. This article explores the Indian patent law procedures, the implications of patenting Ayurveda-related inventions, and the legal landscape surrounding intellectual property (IP) litigation in India. The article begins by stating the general procedure for patent and also documents the relevance of traditional knowledge guidelines for patenting Ayurveda related invention. The article then draws patent applications related to ayurveda as a sample for analysing the patent procedure.

Keywords: *Ayurveda, Patenting, Procedure for Patenting, Traditional knowledge, Traditional Knowledge Digital Library.*

I. INTRODUCTION

Ayurveda is mostly a conceptual discipline, with concepts based on principles of health, etiopathogenesis of diseases, and treatment approaches that include not only medicines but also therapeutic foods and therapies to restore the natural balance of the body.² The main objective of Ayurveda is to “*Maintain the health of a healthy individual by prevention of disease and to cure the ailments*”.³ Ayurveda is based on its own original and unique fundamental principles. Although local herbs and plants have long been used traditionally in medicines in various countries of the world, India has been the pioneer in this field with its ancient medical systems flourishing in codified form for ages and millennia.⁴ Nowadays people have started choosing Ayurvedic medications over allopathic medicines as most of them show side effects.

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²Anand Chaudhary & Neetu Singh, Intellectual property rights and patents in perspective of Ayurveda, 33 AYU (An International Quarterly Journal of Research in Ayurveda) 20 (2012).

³ Mohini Gupta, Vivek Sharma and Harendra Bansal, ‘Role of Ayurveda in the Management of Non-Communicable Disease’ (2022) 7 Journal of Ayurveda and Integrated Medical Sciences 218

⁴Anand Chaudhary & Neetu Singh, Intellectual property rights and patents in perspective of Ayurveda, 33 AYU (An International Quarterly Journal of Research in Ayurveda) 20 (2012)..

Manufacturers simultaneously started attempting to secure patents in various category products related to ayurveda.⁵ However the rules and regulations governing the patenting of traditional knowledge and biological material are affecting the patenting activities in the field of Ayurvedic medicines. Keeping this in view it becomes essential to see how Indian patent⁶ system is protecting the Ayurvedic drugs.

II. RELEVANCE OF TRADITIONAL KNOWLEDGE IN AYURVEDA

In the context of Ayurveda, traditional knowledge (TK) plays a crucial role. The Indian Patent Act includes provisions to prevent the misappropriation of TK:

- Section 3(p)⁷: Excludes the patenting of traditional knowledge or anything that is an aggregation or duplication of known properties of traditionally known components.
- Traditional Knowledge Digital Library (TKDL): A repository that documents traditional medicinal knowledge, including Ayurveda, to prevent erroneous granting of patents and to act as evidence during patent examination.

III. PATENTING OF AYURVEDA IN INDIA

In the Indian subcontinent, Ayurveda is an ancient form of health care.⁸ Ayurveda is a collected system of knowledge and even today people use it on a daily basis. Ayurveda is an Indian system of medicine where most of its knowledge lies in public domain. It generally covers traditional knowledge that has been accumulated through generations. This exists as a major challenge in securing protection as it has to undergo the novelty⁹ and patent eligibility¹⁰ under Indian Patent law. This makes most Ayurveda related inventions ineligible for Intellectual Property protection.

Furthermore, any readymade formula of the traditional Indian Ayurvedic System of Medicine cannot be patented because as per section 3(p)¹¹ an invention, which in effect is traditional knowledge or duplication of known properties of traditionally known components, has been made non-patentable,¹² which means that the Indian traditional medicinal system Ayurveda doesn't qualify for protection under Indian patent laws. However, patents can be awarded for

⁵ Anand Chaudhary & Neetu Singh, Intellectual property rights and patents in perspective of Ayurveda, 33 AYU (An International Quarterly Journal of Research in Ayurveda) 20 (2012).

⁶ Indian Patent Act, 1970

⁷ Indian Patent Act, 1970

⁸ Palaniswamy R, "UNDERSTANDING BASICS of AYURVEDA: A REVIEW" (2018) 9 International Journal of Research in Ayurveda and Pharmacy 154

⁹ Section 2(1)(j) of Indian Patent Act, 1970

¹⁰ Indian Patent Act, 1970

¹¹ Indian Patent Act, 1970

¹² Section 3(p) of Indian Patent Act, 1970

significant advances over traditional medications that meet the standards for patentability set forth in the Patents Act of 1970.¹³

(A) Procedure

Patent application procedure starts with filing of application for patents at the patent office.¹⁴ Applicants can file application for patent at the appropriate Patent Office under whose jurisdiction he/she normally resides or has his domicile or has a place of business or the place from where the invention actually originated.¹⁵ Section 6 of the Indian Patent Act provides who are entitled to apply for patents and Section 7 of the Act¹⁶ deals with filing of application for patent. The application for patent should also be accompanied by a provisional or complete specification.¹⁷ The provisional specification should provide a brief overview of the invention, while the complete specification must describe the invention in detail, including the best method for its use. The complete specification must be submitted within 12 months after filing the patent application.¹⁸ This specification should conclude with one or more claims that define the scope of the invention.¹⁹ Later on the applicant should make a request for examination of the application once the application for patent is published because unlike publication examination is not an automatic process.²⁰ Following the examination, the Patent Office sends the applicant an examination report called as the First Examination Report (FER). It is the applicant's responsibility to address and remove any objections.²¹ The applicant may file a reply statement, after which the evidence-gathering and hearing procedure will continue. The case has been heard and decided. The patent is granted once the examiner finds no objections in the patent application. After that, the patent is open to public inspection.²² Post-grant objections can be raised after the grant of the patent to the applicant based on the grounds which is mentioned in the provisions of Patent Act.²³ Every patent will be valid for a term of 20 years²⁴.

¹³ 'Patents to Traditional Ayurvedic Medicine' (*pib.gov.in*) <<https://pib.gov.in/newsite/printrelease.aspx?relid=98021>> accessed 10th March 2024;

¹⁴ In India, patents are governed by the Patents Act, 1970 and Patent Rules, 2003.

¹⁵ 'Jurisdiction of Patent Offices | Administration | Patents | Intellectual Property India | Government of India' (*Ipindia.gov.in*2015) <<https://ipindia.gov.in/jurisdiction-of-patent-offices.htm#:~:text=An%20applicant%20or%20first%20mentioned>>.

¹⁶ Indian Patent Act, 1970

¹⁷ Section 9, Indian Patent Act, 1970

¹⁸ *ibid*

¹⁹ Section 10(4)(c) of Indian Patent Act, 1970

²⁰ Section 11B(1) of Indian Patent Act, 1970

²¹ Section 15 of Indian Patent Act 1970

²² Section 43 of Indian Patent Act 1970

²³ Section 25(2) of Indian Patent Act 1970

²⁴ Section 53(1) of Indian Patent Act 1970

(B) Guidelines

On November 8, 2012, the Indian Patent Office (IPO) released new guidelines for issuing patents related to traditional knowledge (TK).²⁵ This includes traditional knowledge particularly relating to Ayurveda, Unani and Siddha systems of medicine, etc.²⁶ The IPO was compelled to draft revised guidelines after discovering that some issued patents had to be revoked. These patents were mistakenly granted for inventions related to biological resources sourced from India without adhering to existing laws.²⁷

Before applying for a patent for any invention based on biological resources received from India, Section 6(i) of the Biological Diversity Act, 2002 requires an applicant to obtain prior approval from the National Biodiversity Authority. The National Biodiversity Authority grants such licenses in cooperation with the State Biodiversity Boards, if necessary. Furthermore, before a patent is granted, the Patents Act of 1970 requires an applicant to receive the requisite clearance from the National Biodiversity Authority and submit it to the CGPDTM²⁸ office.

The Patent Act stipulates that the claimed subject matter in a patent application must be new. Another fundamental principle of patentability is the inventive step. It is frequently referred to as the patent system's final doorkeeper. While considering the traditional knowledge-based inventions, guiding principles mentioned in the guidelines must be followed for assessing the novelty and inventive step. Apart from elaborately defining guiding principles it also cites about the patentability and patent eligibility criteria related to protection of traditional knowledge. According to 2 (1) (j) of the Patents Act, 1970, "invention means a new product or process involving an inventive step and capable of industrial application" therefore any invention related to Traditional knowledge does not qualify as an invention. The implication of this provision is reflected on classical ayurveda or already existing ayurvedic formulations where it is essentially traditional knowledge. The Indian Patents Act includes a distinct provision under Section 3(p), stating that "an invention which, in effect, is traditional knowledge or an aggregation or duplication of known properties of traditionally known component or components" is not considered an invention and, therefore, is not patentable under the Patents Act. Further, sections 3 (b), (c), (d), (e), (f), (h), (i) and (j) are of relevance with respect to the patent applications related to traditional knowledge and/or biological material.

²⁵ Bhushan Patwardhan, 'Traditional Knowledge Patents: New Guidelines or Deterrents?' (2013) 4 *Journal of Ayurveda and Integrative Medicine* 1.

²⁶ Guidelines for Processing of Patent Applications Relating To Traditional Knowledge And Biological Material.

²⁷ *ibid*

²⁸ Controller General of Patents, Designs & Trade Marks.

Furthermore, applications for patents based on TK and/or biological material that violate the law can be denied under section 15 or in pre-grant opposition under clauses (d), (f), and (k) of Section 25 (1) of the Patents Act, 1970, and granted patents can be revoked in post-grant opposition under clauses (d), (f), and (k) of Section 25 (2) of the Patents Act, 1970. Under clause (j) of Sections 25 (1) and 25 (2) of the Patents Act, 1970, nondisclosure or incorrect mention of the source or geographical origin of biological material used for an invention in the entire specification is also a ground for pre- and post-grant opposition.

All patent applications involving Traditional Knowledge (TK) must be accurately identified, screened, and designated as "Traditional Knowledge" by the Patent Office's RECS (receiving section) Section. The RECS in-charge must ensure that no case involving TK is improperly screened and categorized. Furthermore, the person in charge of screening must assign appropriate IPC classification to such TK applications so that they can be routed to the appropriate groups for examination, such as Chemistry, Pharmaceuticals, Food, Biotechnology, Microbiology, Biochemistry, Mechanical, and so on. In Every case involving TK requires the Examiner to do a comprehensive search for anticipation in the TKDL and/or other databases. If a citation is made from the TKDL database, a copy of the citation (in English) must be included and sent with the examination report. Given the foregoing facts, as well as the sensitivity and relevance of the matter, it is critical that patent applications using TK and/or biological elements, as well as post-grant actions, be processed with care and attention.

IV. PATENT APPLICATION (STUDY)

Patent Application (221770) - An ayurvedic composition for treatment of hypertension and the heart diseases

Application status	Inforce
Application number	221770
Date of Filing	03/10/2006
Appropriate office	Mumbai
Applicant name	Shankar Sitaram Shepal
Title of invention	An Ayurvedic Composition For Oral Consumption In Treatment Of Heart Diseases And Hypertension
Field of invention	Pharmaceuticals

Request for examination date	22/01/2007
Reply to FER date	11/05/2007
Date of grant	03/07/2008

Details of patent application number 221770 are given in the above-mentioned **Table**. A study of this particular patent application is conducted to analyze the patenting procedure. This particular invention is related to Ayurvedic medication.

In this patent sample the applicant has filed an application for patent along with complete specification and other relevant documents attached to it. The complete specification in this application contains the contents as mentioned in section 10 of Indian patent Act. It contains the ingredients and preparation along with other details. According to the claims submitted at the Indian patent office the invention relates to the field of ayurvedic treatment of heart diseases of vata and kaph origin. Another notable procedure in this application is the early request for publication made by the applicant under section 11A (2)²⁹ vide form 9. Later on for examination³⁰ of patent application request was filed vide form 18. Followed by this first examination report (FER) was send to the patent applicant which contains the objections. Objection 4 and 7 mentioned in FER are relevant for this study as it asks for the permission obtained from biodiversity and states that the claim falls under section 3(p)³¹ respectively. The applicant later filed reply statement to FER. In the reply statement the applicant with reference to objection 4 it was stated that as a citizen of India the applicant is not required to take approval from National Biodiversity Authority of India as provided under section 3(2)a of the National Biodiversity Act. On objection 7 it was submitted by the patent applicant that the invention doesn't attract the provision of section 3(p)³² as all ingredients are in the precise fraction worked out by the applicant. The traditional knowledge offers no information on the said ratios. The patent office found the application in order for grant and hence the patent was granted to the invention.

V. CONCLUSION

The patent procedure under Indian law, particularly in relation to Ayurveda-related inventions, necessitates a careful balance between protecting genuine innovations and safeguarding traditional knowledge. As interest in Ayurveda continues to grow, it is crucial to ensure that

²⁹ Indian Patent Act, 1970

³⁰ Section 11B of Indian Patent Act, 1970

³¹ Indian Patent Act, 1970

³² Indian Patent Act, 1970

patent laws and procedures should evolve to address the unique challenges posed by traditional knowledge, promoting innovation while respecting cultural heritage. While there is no separate procedure for filing patent applications specifically for Ayurveda-related inventions, the traditional knowledge guidelines play a crucial role. The coupling of patent law procedures with traditional knowledge guidelines is essential to prevent the misappropriation of traditional knowledge. Furthermore, the abolition of the IPAB and the transfer of jurisdiction to High Courts represents a significant shift in handling IP litigation, emphasizing the need for specialized expertise and efficient adjudication in the realm of intellectual property rights.
