

Insight Into Intellectual Property in Patent Medicine: An Indian Perspective

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Abstract

This paper aims at exploring intellectual property in relation to patent in medicine in India. Knowledge economy is the engine upon which development and creativity depends that has been instrumental in differentiating countries as developed or underdeveloped. India, being a member of World Trade Organization (WTO) has recognized the importance attached with IP thus investing hugely in intellectual advancement thereby reaping the advantages of second world population. Focusing on three key sectors namely, pharmaceutical, biotechnology, and IT sectors, scholars recognized the contributions these sectors offer to the growth domestic products and economic development of the countries. For instance, in India, many companies are continuously contributing to its economic development and growth at exponential rate. Many issues are discussed with regards to intellectual property.

Keywords: Intellectual Property, Medicine, Intellectual Property Rights, Patents, Trademarks, Copyrights, Copyleft

Introduction

Traditional medicine (TM) is gaining prominence in the contemporary society globally. This is true, as many scholars have noted that traditional medicine is common in Asia and Africa constituting 80% of usage and about 70-80% of populace residing in developed countries have used at least some sort of TM for treatment of ailments¹. This implies that modern drugs and vaccines used for clinical purposes depend mostly on natural resources and are directly or indirectly associated with TM¹ a recognition that TM plays important roles for indigenous people in terms of their social, cultural, and scientific progression. It is clear that, the natural resources abundantly present in nature have no intellectual property rights since they are not the creation of human minds¹. Nevertheless, traditional medical knowledge, which is the creation of human minds has, and thus defined as

“the sum total of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illnesses”^{1,2}

1. World Intellectual Property Organization (WIPO) on Intellectual property and traditional medical knowledge, art. 6. <https://www.ili.ac.in/cstyle.pdf>. (2015).

1^{*}. World Intellectual Property Organization (WIPO) on Intellectual property and traditional

medical knowledge, art. 6. https://www.wipo.int/export/sites/www/tk/en/documents/pdf/background_briefs-e-n6-web.pdf. (2015).

2. World Health Organization Fact Sheet on Traditional Medicine, art. 134. (2008)

This promulgation agrees with Universal Declaration of Human Rights Section 2 in Article 27, which provides thus that, “*Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary, or artistic production of which he is the author*”³. This declaration drew the attention of key players or stakeholders particularly World Health Organization (WHO) and World Trade Organization (WTO) to develop modalities on how to protect indigenous traditional medical knowledge^{4,5}. This is with a view to protecting IP in relation to access and benefit sharing of the genetically abundant resources for healthcare maintenance, improvement, and protection¹.

Even though scholars did not want to define concepts, definitions, at times, prevent diversion. To define patent, as captured by ³ referencing ⁶, patent refers to “*an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem*”. In addition, ³ cited ⁷ who defined patent as

*“a statutory right for an invention granted for a limited period of time to the patentee by the Government, in exchange of full disclosure of his invention for excluding others, from making, using, selling, importing the patented product or process for producing that product for those purposes without his consent”.*⁷

These definitions serve to highlight on the economic gains received by inventors and strengthen the laws given to protect inventions in the pharmaceutical companies and those owned by traditional medical practitioners³. The economic gains are important in increasing the revenue generations of a company and furtherance the investment in R&D to the extent patents are termed the “currency of research”. Perhaps this is the reason why ⁸linked IPR with foreign direct investment (FDI) because of its economic development to nations embracing it across the globe.

To augment on the viability and applicability of this IPR, ¹ cited instances of unauthorized third party infringement where, for example, in India, patents-based traditional knowledge holders on turmeric, neem, and jamun used for healing wounds, antifungal property, diabetes-healing property respectively have been revoked. Similarly, in Brazil, there is a tribe that did not get compensation for using captopril for treating hypertension and heart failure by others, to mention but a few. Furthermore, this proclamation resulted in drafting two forms of IP, i.e. positive and defensive protection. While the former deals with granting the rights to the originator over the subject matter of traditional medical knowledge against illegal intrusion; the latter concerns with documented disqualification, invalidation, or opposition on claimed invention by third parties¹. This indicates the importance of patents to medicine, which are novel, inventive, industrially applicable, and serve as the most important vehicles upon which society benefits, and medical invention receives maximum protection through legislation against infringement¹. In line with this, China patent law protects new traditional products, process of its manufacture, herbal formula, extracts, etc¹.

³ Gerard Marshall Raj & Rekha Priyadarshini, “Drug patents and intellectual property rights” *Eur J Clin Pharmacol* (2015)

⁴ WHO Fact sheet on traditional medicine, art. 134. www.who.int/mediacentre/factsheets/fs134/en/. (2008).

⁵ WTO’s Doha Declaration on Trade Related Intellectual Property Rights (TRIPS) www.wto.org/english/tratop_e/trips_e/who_wipo_wto_e.htm.

¹ *ibid*

⁶ World Intellectual Property Organization on What is Intellectual Property?. <http://www.wipo.int/about-ip/en/index.html#ip>. (2014).

⁷ Intellectual Property India on the Patents Act. http://ipindia.nic.in/ipr/patent/patent_Act_1970_28012013_book.pdf. (1970).

- ⁸ Ivan Stepanov, "Economic development dimension of intellectual property as investment in international investment law", 23 *J World Intellect Prop* 736 (2020). wileyonlinelibrary.com/journal/jwip.

That is why some scholars regard IPR generally as "*a legal sinew of the information age*"⁹. To concur with this fact, ¹⁰ observed that, in India, based on the report of three key sectors with regards to their contribution to economic development due to IP, these authors commented on Ranbaxy (Pharmaceutical Company) founded in 1961, had a total sales of \$1.03 billion in 2004, \$1.2 billion in 2005. Exports accounted for 58% of sales. Its largest markets include Brazil, Russia, and China. It has 28% of sales in US market. Its sales generic drugs are over 100 in foreign countries. Importantly, it has manufacturing operations in seven countries and operating offices in 44 countries. Similarly, Dr. Reddy's Laboratories is the third largest producer in the India. Its net revenue as at 2006 was \$502 million. Dr. Reddy's 66% of revenues are from foreign country markets where 41% of earning derived from formulations. Investing 6.5% of its sales in R&D and it has 7,525 employees¹⁰. Furthermore, in the Biotechnology sector, taking BIOCON as an example, its income from research increased by 52% from Rs. 662 million in 2004-2005 to Rs. 1,006 million in 2005-2006. Its total income increased by 9% to Rs. 7,392 million. Its R&D expenditure increased from 76% to Rs. 764 million¹⁰.

This is the reason why man recognized the importance of knowledge since time immemorial that enabled him to recast ideas and extract something of benefits from thereby doing something that can impact his society positively, and in the modern society, creation of new knowledge gives rise to IPR Divide between developed and developing countries¹¹. In the 21st century, IP is an important determiner of economic development¹¹. To conform to this submission, ⁸ further elaborated on an important scenario where European economic growth rests upon investing in new ideas and knowledge, which opens up ways for investing in technology and product development thereby contributing to economic growth, technology, and innovations. Perhaps this is the reason why ¹² reiterated that, the traditional conception of early intellectual property law has to do with inventions, literary works, artistic works, designs, and trademarks. Worst of all, creation of novel products is challenging, costly, and investing in the unknown risks rejections as the acceptability of the products is hanging before the populace. This is because only small fragments of investments become successful, and infringers duplicate original products with patentability with lesser amounts than the originator. To begin with, in 2004 alone, a US pharmaceutical company spent \$38.8 billion dedicated to research and development¹³. This trend increases year-in-year-out as captured in the World Intellectual Property Indicators' report of 2010. There was a rebound rise in intellectual property filing globally. Similarly, there was a rise in patent filings for 2011, which rose up to 2 million indicating a 7.8% increase on the 2010 records. To eke on the above, there was 13.3% growth rate in trademark filing. For 2012, there was a geographical shift of design, intellectual property, and trademark filings from Germany, Japan, and US to China ¹⁴. Despite there was a global decline of 3% of patent applications globally accounting for 3.2 million patent applications in 2019, this makes China to maintain the hierarchically apex of the spot for about 9 years¹⁵.

⁹ James Boyle, "A manifesto on WIPO and the future of intellectual property", 9 *Duke Law & Technology Review*, 1-12 (2004).

¹⁰ S.K., Verma, and N.V. Muralidhar Rao, "Impact of the intellectual property system on economic growth: Fact-finding surveys and analysis in the Asian region (Country Report – India)" *WIPO-UNU Joint Research Project* (2007).

¹¹ R. Tewari and M. Bhardwaj *Intellectual property: A primer for academia* (Professor Gurpal Singh Sandhu Honorary Director Publication Bureau, Panjab University Chandigarh, India). <https://dst.gov.in/sites/default/files/E-BOOK%20IPR.pdf>. (2021).

⁸ ibid

¹² Peter Drahos, "The universality of intellectual property rights: Origins and development". https://www.wipo.int/edocs/mdocs/tk/en/wipo_unhchr_ip_pnl_98/wipo_unhchr_ip_pnl_98_1.pdf. (1998).

¹³ Amanda Horan, Christopher Johnson, and Heather Sykes, Foreign infringement of intellectual property rights: Implications for selected U.S. industries. Office of Industries Working Paper U.S. International Trade Commission. https://www.usitc.gov/publications/332/id_14_100505.pdf. (2005).

¹⁴ WIPO Economics and Statistics Series on *World Intellectual Property Indicators*

https://www.wipo.int/edocs/pubdocs/en/intproperty/941/wipo_pub_941_2012.pdf. (2012).

¹⁵ WIPO on *World Intellectual Property Indicators 2020*. https://www.wipo.int/edocs/pubdocs/en/wipo_pub_941_2020.pdf. (2020).

From the above, it can be seen how important IP and particularly traditional medicine is to the patentee, community specifically, and globe generally. However, despite importance of traditional medical knowledge in the global scale, there are still areas that experience problems and therefore need further explorations. This prompted many researchers and policymakers to design programs and interventions for imparting positively on traditional medical knowledge. Examples of these strategies include policy, safety, efficacy, and quality, access and rationale use of TM¹⁶, information literacy and awareness on the parts of consumers¹⁷, incorporating indigenous perspectives, medicines, and therapies into primary healthcare¹⁸, traditional knowledge database¹⁹, to mention but a few.

Despite these strategies and programs to integrate TM into the mainstream of healthcare system, still problems exist. The consequences of not addressing these problems result in lack of clear solutions; confusing and contradicting divergent group of national and international policies²⁰. Furthermore, the problems escalate to include irregularities in the design of incorporating pharmaceutical medicines into regulatory systems, safety and efficacy concerns, challenges to ownership, quality control, duration of patent protection, difficulty in differentiating prior art and a claimed invention, which is a step further in ascertaining the inventive stage²⁰, among others. This calls for further researches to look at the problem from a potentially useful perspective. Unless the problem is looked at from the patent agents, the problem of patent for traditional medical knowledge would continue. One of the key scholars who have discussed the issue of patentability in the present days is Robert Sayre.²¹ Some scholars noted that, for an invention to pass through patentability test, patent agent has to understand the invention whether it needs protection or it is just a mere claim.²¹

In order to bring to the limelight of the readers, this paper tries to discuss issues surrounding IP according to the following sub-headings

- An Overview of Intellectual Property and Intellectual Property Rights
- Understanding Patent and Traditional Medical Knowledge
- Patent in Medicine and Traditional Medicine
- Criteria of patentability
- Roles of Patent Agents in Issuance of Patents to Inventors
- Importance of Patenting Traditional Medicine
- Challenges Encountered by Patent Agents
- Future Direction of Patent in Traditional Medicine
- Conclusion

¹⁶ World Health Organization on traditional medicine strategy: 2014-2023.

https://apps.who.int/iris/bitstream/handle/10665/92455/9789241506090_eng.pdf. (2013).

¹⁷ World Health Organization on Guidelines on developing consumer information on proper use of traditional, complementary, and alternative medicine. https://www.paho.org/sites/default/files/pm-who-traditional-medicines-consumer_0.pdf. (2004).

¹⁸ Division of Health Systems and Services Development (HSP) on Traditional, complementary and alternative medicines and therapies: Evaluation Plan of Work 2000-2001 And Plan of Work 2002-2003.

<https://iris.paho.org/bitstream/handle/10665.2/40322/trmeng.pdf?sequence=1&isAllowed=y>. (2002).

¹⁹ Martin Fredriksson, "India's traditional knowledge digital library and the politics of patent classifications", 9 *Law and Critique*, 2021. <https://doi.org/10.1007/s10978-021-09299-7>.

<https://www.diva-portal.org/smash/get/diva2:1565270/FULLTEXT01.pdf>

²⁰ Ryan Abbott, World Intellectual Property Organization on Documenting traditional medical knowledge.

https://www.wipo.int/export/sites/www/tk/en/resources/pdf/medical_tk.pdf. (2014)

²¹ Robert J. Sayre, Introduction and Theory of Patent Claims, World Intellectual Property Organization (Harare, Zimbabwe, 3 September 2019).

<https://www.ili.ac.in/cstyle.pdf>. (2022).

An Overview of Intellectual Property and Intellectual Property Rights

Defining intellectual property rights presents difficulties particularly due to the advancement of technology, adaptability of legal issues, changing dimensions of human innovations and economic development. To begin with, there is a large misconception about what IP entails. Some opine that IP is merely a legal terminology that concerns itself with qualified lawyers and attorneys to debate on or that; IP involves large-scale industries thus neglecting smaller businesses or companies²². Under ideal situation, inventing an idea or technology comes up when an individual or company recognizes a problem and tries to confer solution to it. Based on the innovation cycle as proposed by²³, it is clear that, there is dire need to discover an invention, then develop it in large industrial applications, and deliver it to the public. For a more understanding of the concept intellectual property, a small account is given. IP refers to “*exclusive rights to intellectual capital and creations of the mind*”^{22,28} that encompass artistic works of innovations, computer programs, trademarks, commercial signs, etc.²⁴ of individuals or companies. By offering this definition, it is visible that, it gives intangible entity the features and characteristics of tangible objects thereby assuming their attributes.²⁵ Based on this fact,²⁴ categorized IP into two: industrial property and copyrights and related rights. While the former implies patents for inventions, industrial designs, trademarks, and geographical indicators, the latter deals with rights related to literary, artistic, scientific works including performances and broadcasts. Thus, intellectual property rights refers to the legal rights given to safeguard the original creator of intellectual activity that spins industrial, scientific, literary, artistic, etc.²⁶. In other words, it means the “*set of intangible assets including invention, creation, and contribution to the contemporaneous field of knowledge, which is owned and legally protected by an individual or company from the outside use or implementation without approved consent*”.²⁷ That is why various forms of intellectual property revolve around patents, trademarks, copyrights, industrial design, geographical indicators, semiconductor circuit layouts (designs), trade secrets, etc.²⁸. Government gives patent (monopoly rights) to an inventor for a twenty-year period. Patentability criteria must include novelty, inventive step, and industrial applicability. Trademark is a peculiar indicator used by legally recognized organization for identification²⁸.

The above paragraph indicates clearly that, the secret why the largest economies progress exponentially is their dependency upon the private companies to invent new ideas and set up intentionally or unintentionally the competitive markets [25] that compete with the local and international markets. This is true considering the American progress where Article 1, Section 8, Clause 8 compels Congress to “*promote the progress of science and useful arts, by securing, for limited times, to authors and inventors, the exclusive right to their respective writings and discoveries*”.²⁵

²² Turkey in Horizon, Intellectual property rights: Learn IP rights in horizon 2020.

https://cdn3.euraxess.org/sites/default/files/domains/tr/th2020_ipr_brochure_eng_apr17.pdf. (2020).

²³ WHO, Public health, innovation and intellectual property rights: Report of the commission on intellectual property rights, innovation, and public health.

http://apps.who.int/iris/bitstream/handle/10665/43460/a88438_eng.pdf;jsessionid=A3B413408C87972D3504DAD61A9DBE17?sequence=1. (2006).

²⁴ WIPO, What is intellectual property? https://www.wipo.int/edocs/pubdocs/en/wipo_pub_450_2020.pdf. (2020).

²⁵ Public-Private Analytic Exchange Program, *Intellectual property rights: Public-private analytic exchange program research findings*. https://www.odni.gov/files/PE/Documents/7---2017-AEP_-Intellectual-Property-Rights.pdf. (2017).

²⁶ S.K. Savale, and V.K. Savale, “Intellectual property rights”. 5(6) *World Journal of Pharmacy and Pharmaceutical Sciences*, 2529-2559. DOI: 10.20959/wjpps20166-7102. www.wjpps.com. (2016).

²⁷ The Institute of Company Secretaries of India, Study material professional program intellectual property rights-laws and practices. https://www.icsi.edu/media/webmodules/CRCPP_IPRL%26P_2018_DEC_30.pdf. (2018).

²⁸ Centre for Intellectual Property Rights, Anna University, Overview of intellectual property rights (IPRs): The what, why and how of the

intellectual property rights in a nutshell. <https://www.annauniv.edu/ipr/files/downloadable/Overview%20of%20IPR.pdf>. (2020).

This report recognized and highlighted that pragmatic problem of proactive protection of IP does not guarantee or require practical solution of devoting resources for start-up and small businesses. Rather, product life cycle can be protected from being stolen or infringed through legal, physical, and digital security measures employing employee-consumer education. These can turn risks into opportunities [28].

Understanding Patent and Traditional Medical Knowledge

²⁹have consulted different literature that described invention and brought many varying definitions that this study also found them worthy of sharing. To begin with, the conception of patent and law governing its issuance, does not retain anything of value except if invention emanates therefrom, which is a precondition for granting patent. Thus, invention refers to creation resulting from study or experimentation, a new composition, a device produced through curiosity, or result of scientific investigation, to mention but a few.²⁹ Patentability conditions, which *inter alia* include novelty, inventive steps (non-obviousness), industrial application, etc.²⁹ are important considerations for fulfilling the patent issuance. Many herbal innovators find it difficult to meet the conditions provided by laws.

Traditional knowledge, intellectual intangible cultural heritage, practices, and knowledge systems, or cultural expression is a conglomeration of a large array of disjointed parts that culminated to serve its formation. Among its component parts are art, agriculture, medicinal uses of plants, traditional diagnosis, to mention but a few.²⁰ The practices involved are passed from generations to generations usually documented in public domain or in an electronic format. This implies that, TM is a subset of the superset of traditional knowledge. That is why it is ubiquitously cosmopolitan as it can be found in agricultural, ecological, scientific, technical, medicinal, etc. knowledge.²⁰

Traditional medical knowledge, a subset of traditional/indigenous knowledge, practiced outside allopathic or conventional medicine, is gaining an increasingly prominent impetus in the contemporary society. This is fundamentally due to its relative importance in meeting global healthcare demands and public health needs in most developing countries around the world.²⁰ It attracts a multibillion-dollar international industry where biomedical sector is investing huge sums to extract benefits from this seemingly continuous emerging field, which implies its significance in documenting and protecting it.²⁰ Prior to this development, traditional medicine was at loggerhead with modern IP system put in place to regulate inventions. Realizing the relevance of this field in terms of its financial value, traditional knowledge holders and countries that have genetic resources are increasingly demanding for fair and equitable sharing formula for the distribution of benefits derived from commercialization of the resources and knowledge obtained from traditional knowledge holders.²⁰ A step taken to protect such exploitations was patent, which is the right IP protection for medicine where the inventor enjoys privilege for 20 years¹ from the day of application for patent. This encourages innovation.

Use of traditional medicine and support by WHO resulted from the recognition that, TM is a growing trend for patients, which implies that self-care and proactivity from the sides of patients is highly solicit¹⁷. TM encompasses healthcare practices and products usually of long historic origin developed by indigenous people using plant, animal, or mineral-based medicines,

²⁹ Nadezda Ljubojev and Sinisa Varga, "The patent law conception of invention", 17(6) *Metalurgia International*, 160-165. https://www.researchgate.net/publication/293349263_The_Patent_Law_conception_of_invention. (2012).

²⁰ *ibid*

¹⁷ ibid

or techniques designed to treat illnesses or improve wellbeing and health.²⁰ In many cultures around the world, such practices have been in existence for hundred or even thousands of years. For instance, Ayurveda in India, traditional Chinese Medicine, traditional Arabic (Unani) medicine²⁰ have been practiced by generations after generations. This implies that, TM has been an inspiration for the development of many aspects of modern medicine. As characteristic features of TM, they have holistic and individualized approach to healing engaging individuals as active participants in their own health. Following underlying basic rules, TM can function in addressing physical, mental, spiritual attributes of ailments and emphasizing the importance of prevention and wellbeing as a prerequisite for general individual health.²⁰ Even though there are regional discrepancies, TM, controlled by state and national policies, involves some forms of trainings with different cultural beliefs; which have varying degrees of evidence-base and efficacy. This makes TM to be a source of income for many communities and as identity of such a community. However, in addition to its advantages, there are practices considered negative and dangerous that call for further researches for documenting them appropriately.²⁰ This signaled World Health Organization to suggest precautionary measures to take into consideration prior to developing drugs, which include— a) investigation, b) activity planning, c) development of materials, d) material testing and revising; e) activity implementation and monitoring, and f) activity evaluation and assessment.¹⁷ It is important to note that, the information needed to increase proper use of TM varies from country to country, which depends *inter alia* on traditional influences, health system structure, pattern of using TM.¹⁷

Natural products have been serving important roles right from antiquity to present era. Modern technology has proved effectiveness in isolating important components and manufacturing synthetic drugs from natural products.³⁰ However, development of drugs from modern techniques began to fade nearing impossible in certain circumstances and necessitating return to natural products for chemistry-based products because of presence of biological activities and drug-like products.³⁰ This implies their continued relevance in the contemporary society for meeting effective drug development that can fight critical diseases.³⁰ For centuries, more than 60,000 years, man has been using natural products as drugs extracted mainly from plants, animals, microorganisms, etc. to cure or prevent diseases that bedevil him, which is an important indicator for survival of the species. Modern medicine benefits from TM in that, it incorporates drugs into its mainstream especially those that have similar effects and those without.³⁰ This synergistic relationship between TM and modern medicine indicates that, in the future, there would be a possibility where same natural products have medicinal values but understanding the mechanisms of actions of these natural products will challenge practitioners. In other words, there is more to learn from natural products necessitating establishing a *large compound library for drug* screening owing to the advancement in technology particularly pharmacodynamics, fermentation, coupled with biodiversity, chemo-diversity, and improvement obtained in evolutionary identification and characterization techniques.³⁰ Critical examinations if these factors reveal that, there are many difficulties or even impossibilities to encounter in unraveling the mysteries inherent in these natural products. This is true considering large amount of data, documents, and sometimes-useless rumors. In addition, a single plant, or isolated natural products, or TMs may have synergistic effects, which significantly shows the need for careful observation to eliminate the garbage and take the most essential component.

¹⁷ ibid

²⁰ ibid

³⁰ H. Yuan, Q. Ma, L. Ye, and G. Piao, The traditional medicine and modern medicine from natural products, 21 *Molecules*, 559. www.mdpi.com/journal/molecules (2016).

In practice, most natural products and TMs have synergistic effects, which dispels the notion of “*I disease, I drug, I target*” to a more accurate “*multi-drug and multi-targets*” for treatment of critical diseases like heart diseases and diabetes.³⁰ Examples of compounds extracted from natural products include but not limited to romidepsin, Camptothecin, irinotecan, topotecan, taxol, docetaxel (functioning as anti-tumor), schisandrin C, bicyclol, bifendate (anti-hepatitis B virus), lovastatin (hyperlipidemia), ginkgolide B (cerebral infarction), stilbene glycoside (vascular dementia), ternatolide (anti-tuberculosis), to mention but a few.³⁰ These discussions are enough to suggest the intricacies and mysteries to encounter for selecting appropriate TM for issuance of patent for innovations. In other words, it portrays the patent agents to possess peculiar skills, expertise, and knowledge to segregate the dross and select the essence as par the patentability is concerned.

Patent in Modern and Traditional Medicine

For long, scholars observed that, the relationship between local communities or developing countries and IP system is very antagonistic. This is true as they engage in debates around peripheral knowledge protection system, which seems to be either collateral to or independent of IP system. This prompts them to display attitudes that are admiration, disaffection, or resistance.³¹ This is to the extent that they expand the frontier of IP where they try defend, expand, or even offend it to include poor people’s knowledge in the IP framework. This foe arose due to the failure of the IP system to recalibrate non-western (traditional) knowledge as a self rather than non-self where a large portion of resources are transferred from developing countries to western world with no any consequential benefits to the former, which necessitated these developing countries to rise up at national and international level to protect their knowledge form.³¹ Using Cultural cosmopolitanism,³¹ was able to discern absence of difference between knowledge system. As a result of the pressure mounted upon IP system and recognition of the empirical support and appealing credibility by local content defenders brought about opening opportunity equating traditional knowledge with western knowledge systems. The implication of negating traditional knowledge results in zeroing the contributions made by local communities into the domain-specific environment of western medicine thereby leaving them to *mine their prides in religious depths*^{31, 32} instead to anneal the “*single hardened line of vehement division*”.^{31, 32}

India occupies one of the most important place in the cultural heritage and traditional medicinal knowledge. From traditional medicinal perspective, India is known for many medicinal traditions that revolve around Ayurveda, homeopathy, naturopathy, Siddha, Unanani, and Yoga. The knowledge domains propagated through oral tradition are in classical documents translated in Hindi, Sanskrit, Urdu, Tamil, to mention but a few.³¹ This made them to be accorded public domain recognition where many transnational pharmaceutical bodies and research institutes use it via patent system, which drew many controversies especially at the US Patent and Trademark Office (USPTO), the European Patent Office (EPO), and many other countries.³¹ This drew the attention of India to draw a line on bio-piracy following the evidence gathered from different developing countries concerning genetic resources and traditional knowledge heritage.³¹

³⁰ *ibid*

³¹ Chidi Oguamanam, “Patents and traditional medicine: Digital capture, creative legal interventions, and the dialectics of knowledge transformation,” 15(2) *Indiana Journal of Global Legal Studies*, 489-528. <http://muse.jhu.edu/journals/gls/summary/v015/15.2.oguamanam.html>. (2008).

³² Amartya Kumar Sen, *Identity and Violence* 16 (2006).

This resulted in the establishment of defensive anti-appropriation strategy, the Traditional Knowledge Digital Library (TKDL), which is interdisciplinary and interdepartmental and warrants

codifying inaccessible Indian traditional medicine digitized to prevent further bio-piracy of the patents. The rationale for its formation is among other things to ensure that,

“[t]he project . . . involves the documentation of the knowledge available in [the] public domain on traditional knowledge from the existing literature related to Ayurveda, Unani and Siddha, in digitalized format in five international languages which are English, German, French, Japanese and Spanish.”³¹

The concern of this software is to bridge the gap between antiquity and the modern society and to avoid accepting minor contribution as a novelty.³¹ thus puts it where he referenced V.K. Gupta, who noted that,

“TKDL database acts as a bridge between ancient traditional knowledge in the original languages (which may be in Hindi, Sanskrit, Urdu, Persian, Arabic, Tamil, etc.) and a patent examiner at a global level, since the database will provide information on modern as well as local names in a language and format understandable to patent examiners. The gap in prior art knowledge is minimized. The prior art has sufficient details on definitions, principles, and concepts to minimize the possibility of getting accepted minor insignificant modifications as novelty.”³³

Understanding the study conducted by³³ will reveal a rather myriad of mixed sacrifices done by the former generations, traditional knowledge classifiers, those versatile and conversant with international patent classification, IT, science, research, bureaucracy, as well as governments not only in documenting TM but also inculcating the practices in their contemporary generations to the present day generations. In other words, they ensured that the treasure of such knowledge does not lose vigor rather maintained and passed on from generations to generations. Furthermore, these scenarios indicated that, TM and modern medicine are inseparable entities and activities of one complement the other. The viability of TKDL is conspicuous as it connects directly with *IP office of search and examination of prior art search system*.³¹

³¹ *ibid* (for detail, see 31)

³³ In March, 2007, Vinod Kumar Gupta conducted a study and identified that there were about 148 books whose contents contained 230 volumes of Ayurveda, Unani, Siddha, and Yoga. These served as a skeletal element for the TKDL project. This is to the extent that 64 books of the 90 volumes addressed Ayurveda indicating about 76,000 formulations. TKDL derived from 19 books of 16 volumes is in the same format and language with Ayurveda. The language used for both were Urdu, Arabic, and Persian. Targeted formulation for Siddha were anticipated to be 12,000 obtained from 45 tamil texts of 53 volumes. Yoga TKDL projected to be emanate from 150 posture images from 20 books where 24 million pages of information have been created out of the projected 31 million pages as at 2007. Vinod Kumar Gupta, India, TKDL: Definition and Classification of Intangible Cultural Heritage and Traditional Knowledge in the Context of Inventory Making (paper presented at the Conference on Intangible Cultural Heritage and Intellectual Property Under the 2003 UN Convention for the Safeguarding of Intangible Cultural Heritage, New Delhi, India, March 25–27, 2007).

Criteria of Patentability

Patent laws are different in different countries, which make the patentability requirements different in different countries globally. However, there are major three criteria used to patent an invention drafted by US, and are: novelty, usefulness (utility), and non-obviousness.³⁴ These are important for patent agents in considering the rightfulness of an invention to qualify for patent. To begin with, novelty, prescribed by USPTO, WIPO, EPO, deals with newness of an invention that was previously unknown and unavailable to public prior to filing for patency. It has to be different from the previous inventions or at least add something new to, for instance, the known processes, machines, among others.³⁴ In addition, when two or more inventors invent the same thing, priority is given to the first who claims patency but has to explain it theoretically and reduce it to practice. Only then qualifies him/her for the patentability of the invention. Otherwise, the patency will go to the second inventor who beyond reasonable doubts explicates everything associated with the invention. If they equalize in reducing the invention to practice, but differ markedly on the account that, the second invention works faster than the first, the patent will be given to the first inventor.³⁴ Secondly, there is issue of usefulness or utility. It implies that an invention must possess some form of usefulness or else, lacks patentability. For US, there are three sub-criteria with respect to invention to qualify for patentability. These are general, specific, and moral or beneficial utility. For the former, the invention must be able at doing something. For the second, the invention must solve a specific problem it is designed to confer solution to. For the latter, the invention should have a minimum of social benefit, or at least, not to be a detriment to the society and humans.³⁴ Thirdly, for patent applications in art and science, they must pass through non-obviousness test in that, the invention should pass the level of person with ordinary skills in the field. This implies that, it has to show something of surprise and unexpectedness to the ordinary people in the profession. This is very difficult to measure. Thus, the courts consider many things to be obvious such as substituting the superior for inferior, changing the size or dimension of a machine, etc.³⁴ To be precise, the exceptions attached to patentability are discoveries, mathematical theories, aesthetics creation, playing games, software, methods of doing business, therapeutic and diagnostic procedures, inventions contrary to morality, to mention but a few.³⁵

From the above, it appears that, patenting refers to a strategy of protecting an innovation without secrecy for a period of 20 years from the application filing dates.³⁵ It is a social contract that is implicit where it encourages revealing the invention to the general public that allows others to invent and improve more on the invention and ensuring exclusivity to the inventor.³⁵ It has potential of improving innovations, strengthening economy, creating jobs, among others. The rights conferred by the patent prevents others from making, using, selling, or importing infringed materials. The patent rights does not apply to inventions done privately and not for commercial purposes, does not support infringement unless permission is sought from the owners, and requires all inventors to subject themselves to patent search to avoid wasting time, energy, and resources. Summing all the above statements, ³⁶ noted that, there are patentability criteria in patent system that include formality requirement (form and content of application, procedural requirement), unity of invention, patentability criteria (patentable subject matter, novelty, inventive step, industrial applicability, sufficiency of disclosure), and prohibition of double patenting.³⁶

³⁴ Umakant Mishra, Three tests of patentability, TRIZsite Journal, 2006.

³⁵ World Intellectual Property Organization, Topic 3 - Chapter II.B Legal Requirements for Patentability. https://www.wipo.int/edocs/mdocs/africa/en/wipo_pat_hre_15/wipo_pat_hre_15_t_3.pdf. (2015)

³⁶ Tomoko Miyamoto, Patentability Criteria and Patent Grant Procedures at Country Level. https://www.wto.org/english/tratop_e/trips_e/miyamoto_trilatworkshop15_e.pdf. (2015).

In India, in March 2005, the government introduced the 2005 Patent (amendment) Bill in the parliament to meet the international obligation on Trade-Related Intellectual Property Rights (TRIPS Agreement). The journey to meeting the deadline was long due to the transition of government from BJP (who noted in 2003 under National Democracy Alliance) to UPA (who feared that if the Bill had to pass through the Parliament, it would upset the deadline set by the TRIPS Agreement. This action was repelled and the Bill had to be brought back for assenting to presidential ordinance where the Left Parties debated this stance and caused a stir in this regard).³⁷ There was a serious debate concerning microorganisms and pharmaceutical products. For the latter, a committee, headed by Mr. Kamal Nath, was set up to reconsider the definitions associated with pharmaceutical products as either *new medical entity* (NME) or *new chemical entity* (NCE). After careful scrutiny, the Bill was passed in the 3rd week of March 2005 as the Patent (Amendment) Act, 2005. On the issue of pharmaceutical products, in December 2006, the expert committee advised that, “*limiting the grant of patents for pharmaceutical substance to only new chemical entities was not compliant with TRIPS, and excluding micro-organisms from patent protection would be violate TRIPS.*”³⁷ These suggestions also received maximum reactions as some observed that, the report described many things unnecessarily than explain. To calm down the nerves of both opposing and supporting the TRIPS, ³⁷ conducted a research from legal perspective to checkmate the rightfulness of either side. The researcher found that, the Technical Expert Group on patent issues were in congruence with the provisions in TRIPS Agreement. The only handicap experienced by the group was lack of tallying their evidence with legal provisions.³⁷ From another angle, in India, the requirements for filling patent are novelty, usefulness, non-obviousness, industrial applicability, and adequate disclosure.³⁷

Roles of Patent Agents in Issuance of Patents to Inventors

Critical examinations and statistics of filing applications around the world clearly indicate the relevance and necessity of patent agents in the process from both global and territorial perspectives. This agrees with ¹⁵ where the number of applications is exponentially increasing. In addition, this trend makes China to maintain such a first position as indicated somewhere above.¹⁵ From the technical perspective, patent agency is a work that entails almost the entire process of issuing patents to applicant. Looking at the definitions offered by ³⁸, it follows that, patent agent involved in patent activities ranging from processing patent filing applications, patent grants, patent renewal procedure under the Patent Office, i.e. Office of the Controller General of Patents, Designs, and Trademarks governed by the Indian Patents Act, 1970. Before, the patent agents used to be graduates of law schools however; subject specialists (specifically chemistry, physics, biotechnology, engineering, etc.) now participate in the activities. They have to write examinations to qualify them for this post under the Patent Office.³⁸

Among the roles of patent agents is to help client secure legal protection for their invention by filing appropriate patent application and do the same for registration. Such a registration can be in the country of residence of the applicant, place of business, or abroad.

³⁷ Rajnish Kumar Rai, Patentable subject matter requirements: An evaluation of proposed exclusions to India's patent law in light of India's obligations under the TRIPS Agreement and options for India, 41 *Chicago-Kent Journal of Intellectual Property*, https://studentorgs.kentlaw.iit.edu/ckjip/wp-content/uploads/sites/4/2013/03/03_8JIntelProp412008-2009.pdf. (2008).

³⁸ Manisha Shridhar, Sudhir K Jain and Vinayshil Gautam, “Patent activity by patent agents in India”, 14 *Journal of Intellectual Property Rights*, 142-148. http://www.nbpgr.ernet.in/assets/pdf/IPRarticle/014_patent_agents.pdf. (2009).

¹⁵ *ibid*

³⁹ https://www.wipo.int/edocs/mdocs/africa/en/wipo_pat_hre_15/wipo_pat_hre_15_t_1.pdf.

In other words, patent agents serve as the legal representative of client in any issue that has to do with application at national or regional office of the Patent Office. In addition, it is the responsibility of the patent agent to draw and sign any documents and where possible, communicate with, and represent clients in all dealings with Patent Office. To qualify for these responsibilities therefore, the patent agent has to understand in and out of the invention and technicalities involved in. This is because, understanding the invention will assist patent agent in drafting a technically good patent application. To ensure that, patent agent has to know the field of invention and guarantee that, he understands the invention from all angles deemed appropriate to qualify it for securing patentability.³⁹

It is equally important to note that, in India, to indicate how committed she became with issues of patentability; there are four divisional offices of Patent Office that have officers and employees of varying levels and duties. For instance,⁴⁰ has mentioned a great deal of officers, and their duties in a chronological order. These include Controller General of Patents, Designs, and Trademarks (CGPDTM), Senior Joint Controller of Patents & Designs, Joint Controller of Patents & Designs, Deputy Controller of Patents & Designs, Assistant Controller of Patents & Designs, Examiner of Patents & Designs, Hindi Officer, Administrative Officer, Assistant Library, and Information Officer, to mention but a few.⁴⁰ All these staff have coordinated activities and roles of one officer might be linked up with another officer but geared towards meeting the needs of the inventor for patentability of his/her inventions. It has to be made clear here that, there is synchrony between Indian and US regulations governing patent agents. This is evident in the document titled “United States Patent and Trademark Office, Office of Enrollment and Discipline (OED)” wherein the details of scientific and technical trainings required for admission into the examination, categorization of officers, filing deadline, etc. are captured.⁴¹

Furthermore, the genesis of patentability can be traced to late 19th century where for a potential patentee no matter how scientifically and technically qualified could not prepare specifications without assistance from qualified people with thorough knowledge of legal procedures. That was the prime and ripe time for patent agents to establish themselves as professionals where a joint task force between lawyers and qualified engineers formed a strong profession for patent litigation and industrial controversies as regards inventions.³⁸ This brought about the formation of a single body of lawyers and engineers that gave rise to a London-based Institute of Patent Agents in 1882 and this strengthened gaining recognition and securing a register compiled by Board of Trade in UK in 1889. At the end of the 19th century, a degree in science or engineering was regarded as a prerequisite for patent agent curriculum. The conclusion of their study suggested that, biotechnology firms file and obtain large number of patents while for textiles, garments, accessories, leather, ceramics, etc. patents file are zero. This suggests that, patent filing is directly proportional to the type of industry category.³⁸

³⁸ Manisha Shridhar, Sudhir K Jain and Vinayshil Gautam, “Patent activity by patent agents in India”, 14 *Journal of Intellectual Property Rights*, 142-148. http://www.nbpr.ernet.in/assets/pdf/IPRarticle/014_patent_agents.pdf. (2009).

³⁹ https://www.wipo.int/edocs/mdocs/africa/en/wipo_pat_hre_15/wipo_pat_hre_15_t_1.pdf.

⁴⁰ <http://ipindia.gov.in/writereaddata/images/pdf/office-of-cgpdtm.pdf>.

⁴¹ United States Patent and Trademark Office Office of Enrollment and Discipline (OED). General Requirements Bulletin for Admission to the Examination for Registration to Practice in Patent Cases before the United States Patent and Trademark Office. https://www.uspto.gov/sites/default/files/documents/OED_GRB.pdf. (2008).

Importance of Patenting Traditional Medicine

Importance of patenting TM can never be overestimated. Looking closely at the previous works of this subject matter reveals the relevance of TM in the contemporary society. To start with, necessity is the basic rationale that compels humans to invent monopolies in method of treatment and medicines, benefit from increasing market frontiers, survival of the fittest or smartest where some competitors exit markets, among other issues.⁴² From pharmaceutical viewpoint, patentable substances must meet these requirements for them to be patented. These requirements are new process of production, new formulation processes, new composition of matter, new chemical entities. For instance, in India, new use of known herbs are patentable if there is novelty in the dosage forms/formulations, or synergistic combinations. In Europe, in addition to these, there must be efficacy in new indication. Whereas in America, it must qualify a process of treatment.⁴²

There are many calls from scholars to avoid taking synthetic antibiotics because of their side effects. Patenting TM can at least reduce such chances and free human race from the shackles of diseases if used appropriately. Example, patentable natural products have potentials for reducing serious diseases such as allergies, weight loss, appetite suppressants, among others. This implies that, Indian scientists and research labs can collaborate in producing advanced medical treatment and can partner with America, Europe, etc. Through sustainable development goals, India can use sustainable models to enhance herbal resources development, and can garner support in sharing different business models for the benefit of collaborating countries.⁴²

Covid-19 pandemic has shown the world that collaboration is the ultimate goal required between all sectors geared towards solving problems that confront the planet earth. These challenges can be medically, socially, environmentally, economically, etc. inclined. The ultimate goal is to unite as one and face such an obstacle head-on. The recognition that public health is a global not a regional challenge calls for cooperation.⁴³ In support of this thesis, WHO, WIPO and WTO have identified ways through which these could be authenticated. For instance, the report outlined areas that can impact humanity and environment such as access to medicines and rights to health where the global burden of diseases necessitates rapid response system. These include measures to contain costs and improve access to health facilities, regulations of health technologies, invention in medical technologies, in-depth research, and innovation gaps into neglected diseases, paradigm shift in terms of thinking on industrial roles in curtailing diseases. The report further indicated that IP mainly patents can have impact on public health especially if combined with effective competition and access thereby increasing free trade agreement among nations.⁴³

⁴² D.N. Raut, Herbal drug patenting, <https://www.amrutpharm.co.in/doc/ppt/2019-20/patenting.pdf>. (2019).

⁴³ World Trade Organization, World Health Organization, World Intellectual Property Organization, "Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade" (2nd ed.). https://www.wto.org/english/res_e/booksp_e/who-wipo-wto_2020_e.pdf. (2020).

Challenges Encountered by Patent Agents in India

Even though there are a lot of literature that describe activities of patent agents, little or no literature highlighted problems encountered by patent agents in executing their assigned duties. Most literature dwells more on patent applicants. Perhaps this is so because, the body presumes that

patent agent must have specialization and qualifications that can equip him/her to discharge assigned duties positively and that, as indicated above, there is a strong relationship between patent applicant and patent agent whose can serve the role of lawyer to the patent seeker. Fortunately, the study conducted by ⁴² highlighted some of the challenges encountered by not directed to patent agents but seeker. The paper will try to link these challenges with patent agents.

- i. Resistance from powerful Ayurveda lobbyists industrially and professionally: There is a triangular relationship between Ayurveda professionals, industries, and those trying to justify patentability. This results in the Ayurveda lobbyists to resist any invention that is closer to their patents.
- ii. Poor standardization and characterization: If the standard tool required differentiating one innovation from another, this can set patent agents at cognitive disequilibrium.
- iii. Lack of clear regulatory guidelines: This mostly arises when the top authorities fail to update and incorporate newer and emerging technologies into the mainstream of guidelines that can assist patent applicants
- iv. Patent literature analysis of TM is 70-75% in China, 10-15% in Japan, 5-10% in Korea, 2-5% in India, and the rest in Africa and Latin America. This is a challenge for patent agents to ensure maximizing availability of literature that can inform public thereby improving on innovations as per the TM is concerned
- v. Limited patenting opportunities: Because of the resistance by the Ayurveda lobbyists, this restricts patenting opportunities. Patent agents should devise a means of reconciling these established bodies and patent applicants to shift ground for the betterment of themselves and society as well

Future Direction of Patent in Traditional Medicine

Industry and policymakers are working tirelessly to revamp the India's next stage of growth in innovation focusing on a nexus between innovation and competitiveness. This is to set India further at the global competitive end thereby drawing investments especially through FDI. It is true that national IP draft should set India on a positive direction pertaining IPR regime. There is the need for establishing well-suited IPR courts staffed with appropriate personnel that can strengthen IP and innovations. There should be presence of policies that can encourage investment in IP and innovations.

⁴² *ibid*

Having enumerated these legal provisions it is important to consider the future of innovations to see whether it holds something tangible for the aspiring creators and innovators. Fortunately, since 2004, there has been a Geneva proclamation on IP that fueled these tremendous innovations in a number of ways and domain-specific environments. The manifesto clearly indicates that humanity

witnesses remarkably global crises in the governance of knowledge, technology, and culture, which resulted in the following declarations:

- Without access to essential medicine, millions suffer and die
- Inequality in access to education, knowledge, and technology impedes development and social cohesion
- Anti-competitive practices in the knowledge economy burdens consumers and bring about retarded creativity
- Copyrights holders face immeasurable barriers to follow-on innovations
- Restrictions to access knowledge, technology, biological resources, and development do more harm to development
- Technological measures taken to enforce IPR are a threat to copyrights for People with disability, libraries, educators, etc.
- There is a mismatch between compensating and supporting creative minds and communities.⁴⁴

It is conspicuous that, the future of Indian patent application is rewarding looking at the pharmaceutical, biotechnology, IT, Artificial Intelligence, agro-allied chemicals, etc. All these sectors have potentialities of transforming the IGR of India and expose indigenes into innovating thereby adding values to the country's GDP and attracting exportation.

Conclusion

It is clear that, based on the frequent amendments by Indian government, there is possibility that, India will lead in the next few years in terms of patent filings and creativity. However, government has to strengthen the ties between agencies responsible for patent filing and media for continuing enlightenment campaign geared towards creating awareness to populace for creativity and innovation, which is beneficial to individuals in particular and country or globe at large.

⁴⁴ Geneva Declaration (2004). Geneva Declaration on the Future of WIPO. https://www.iatp.org/sites/default/files/451_2_37319.pdf.