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**Traditional Medicine and Intellectual
Property Rights
Law and Policy Perspectives**

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Traditional Medicine and Intellectual Property Rights

Law and Policy Perspectives

T. C. James*

Abstract: Discussions in the past on Traditional Knowledge and Traditional Medicine focussed more on defensive protection against misappropriation. In recent years, many have been exploring the possibilities of positive protection, particularly for TM. This paper examines the current status of intellectual property protection for traditional medicine, especially the Indian systems like Ayurveda; issue of innovation in these systems, and challenges and risks in patenting TM and concludes with suggestions for the way forward.

Keywords: Ayurveda, Patent, Guidelines, Challenges, Risks, Traditional Knowledge.

Introduction

Protection of the Traditional Knowledge (TK) and extension of economic and social benefits to the TK holders have been attracting the attention of policy makers at national and international levels for many decades now. The misappropriation of the TK, more particularly Traditional Medicinal Knowledge (TMK), by the modern pharmaceutical industry, has been a major concern and the Convention on Biological Diversity (1992) made provisions for TK associated with biological diversity by declaring the same to be within the sovereign rights of each country. Since then, the discussions moved on to how Intellectual Property Rights (IPRs) can be granted to TK just like to modern pharmaceutical and other inventions and innovations. Since the subject has domestic and global implications

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issues relating to the IPR protection of Traditional Medicine (TM) must be examined from international and national perspectives for the following reasons:

- IPRs are part of international law; the obligations of countries arise from their ratification of international treaties.
- TM exists in a large number of countries.
- There are already certain international treaties that extend protection to TM associated with the biological resources.
- The exploitation of TM knowledge happens in many countries.
- There are on-going discussions at international fora on protecting TM knowledge.
- All Intellectual Property (IP) laws are territorial.
- India has a strong TM system.
- There are also national laws which regulate the exploitation of TM knowledge.

This paper first discusses the international dimension of IP protection for TM as a backgrounder to the later sections dealing with the domestic status, concluding with the rationale, challenges, and way forward from a national perspective.

Intellectual Property Rights

The emergence of capitalism¹ in place of feudalism², in a post-Industrial Revolution Europe and the rise of nation-states, necessitated rule-based protection for innovations, creative works and commercial marks used in trade and commerce. That was the beginning of IP laws. Patent and copyright laws came up in various countries of Europe during the 15 to 18 centuries, starting with the Venetian Patent Statute of 19 March 1474 (Nard and Morriss: 2006). In England, the Statute of Anne dated 10 April 1710³ granted book publishers copyright protection. The Constitution of the United States of America (USA), drafted in the year 1787 (and ratified in 1788) provided for IP protection in the very first

article itself⁴. India had its first copyright law in 1847 and patent law in 1856. In 1883 the Paris Convention for the Protection of Industrial Property, the first major international agreement on IP, which covered patents, trademarks, industrial designs, and appellations of origin came into existence. Soon in 1886, the Berne Convention for the Protection of Literary and Artistic Works ensued. This provided for copyrights and related rights. These were followed by several specific treaties on different IPRs. The Universal Copyright Convention (UCC) was finalized by UNESCO in 1952. The World Intellectual Property Organisation (WIPO) was set up as a specialised agency of the United Nations to handle all IP treaties and conventions in 1967.⁵ As of 30 September 2022, it has 193 Member states. The International Convention for the Protection of New Varieties of Plants was adopted in 1961. A comprehensive treaty, namely, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), was finalized in 1994 and is administered by the World Trade Organisation (WTO). This Agreement lays down standards, scope, and use of IPRs for the following categories: Copyright and Related Rights, Trademarks, Geographical Indications, Industrial Designs, Patents, Layout-Designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information, and Control of Anti-Competitive Practices in Contractual Obligations.⁶

Two important features of international IP agreements are that they provide for minimum levels of protection obligations and national treatment. While all member states of an agreement are to provide the minimum levels of protection provided in the agreement, they are free to provide higher levels of protection. The national treatment clause provides that under IPR laws, there can be no discrimination between nationals and foreigners.⁷ Therefore, if IP protection of traditional medicine products is extended to Indian nationals by India, the same treatment will have to be granted to nationals of other countries. Unlike the case with earlier IPR treaties, the TRIPS agreement also provided for a dispute settlement mechanism⁸ and imposition of penalties on a country that did not fulfil its treaty obligations.

The IPRs extend positive protection to the subjects that fall under the scope of the same. These include scientific inventions, artistic designs on articles, commercial marks used on traded goods, creative expressions in literary and artistic fields, performances of artists, trade secrets, geographical indications, and plant varieties. The laws lay down certain criteria under each category for making a subject eligible for protection, namely, novelty, inventiveness, and industrial application for an invention, novelty or originality for an industrial design, distinctiveness for the marks used on a traded good and originality in a literary or artistic expression. Mostly, these criteria tend towards something new or original, though in the case of geographical indications it is for an existing product which has certain distinctiveness. Almost all IPRs are granted as a bargain for making the product or work public, though in the case of trade secrets, the condition itself is that it is not made public by the owner.

The IPRs incentivize investment in innovation and creativity by granting exclusive rights over them to the inventors and authors. This encourages commercial activity by attracting investment to the industries that rely on them such as publishing and manufacturing of new products. Business firms can acquire the rights over new products and works through licences and assignments. The rights ensure that the owners and licensees can take legal action against the infringers. IPRs indirectly serve as investment protection rights.

At the same time, IPRs have many limitations, such as they are territorial and temporal. The rights available under a national legislation are restricted to the territory of that country and are independent of protection in other countries.⁹ They also have temporal limitations. Patents are for 20 years only.¹⁰ In addition, the national legislation can exclude from patentability.¹¹

- An invention whose intended use is against *ordre public* or morality
- An invention, exploitation of which may affect human, animal or plant life or health.

- Diagnostic, therapeutic, and surgical methods for the treatment of humans or animals.
- Plants and animals, other than microorganisms, and essentially biological processes to produce plants or animals except for non-biological and microbiological processes.

Further, patents do not cover all knowledge. Scientific theories, mathematical principles, business methods and so on are not covered. Ideas as such do not stand to get protection. IPR is extended to new products and processes and original creative works or distinctive marks and not to existing knowledge, processes and so on.

It is the early industrialised countries that were at the forefront for IP protection¹², and they did not include items on which they were not in a competitive advantage. This has been a determining factor in setting the eligibility criteria for various IPRs. The knowledge of traditional societies such as traditional knowledge or folklore or cultural expressions (e.g., Indian music) or TM did not qualify for this new form of legal protection. This created a distorted system of laws which denied protection to the knowledge of the global South while to access the knowledge of the global North, the South has to pay royalties. A glaring example of this is the traditional medicinal systems of the world. Even the eligibility criteria for many IPs were also drafted in such a way that the major products and practices of the developing world were excluded from eligibility. The international IP conventions do not contain provisions for granting patents to TK although they recognize and would protect modern industrial products generated from that knowledge (Mugabe: 2001). Thus, as per US law, until 2012, prior knowledge or use in the US only was eligible as prior art; the existence of a product or knowledge among the public in other parts of the world was not considered prior art.¹³

Traditional Medicine

Unlike the case with IPRs, Traditional Medicine has a long uninterrupted history. It may go back to very early days, the times when humans were

hunter-gatherers. The origin may be from the search of early humans for remedies for their various illnesses. Through a method of trial and error, and dictated by the knowledge preserved in their genes, they might have developed various medicines, mostly of herbal origin. Based on archaeological evidence some trace the origin of the use of plants for medicinal purposes to more than 60,000 years, and written records are traced back to about 5000 years to the Sumerians (Pan *et al*: 2014). As the medicinal knowledge expanded in course of time some of it got streamlined into various systems. We thus have Ayurveda, Yoga, Siddha, Unani, Sowa Rigpa and so on in India itself. Other countries also have their systems including Traditional Chinese Medicine. Chiropractic and Homeopathy, though not exactly TM, are considered complementary medicines and are usually clubbed with TM.

Traditional Medicine (TM) and Traditional Knowledge (TK) are closely related. While Traditional Medicine Knowledge (TMK) is TK, all TK is not TMK. It is much wider than TMK and includes knowledge in the areas of agriculture, environment, handicrafts, handlooms, folklore and so on. While accepting that so far there is no universally acceptable definition of TK, WIPO in its Glossary relating to Genetic Resources, TK and Traditional Cultural Expressions¹⁴ says that the expression “Traditional knowledge,” is “a broad description of subject matter, generally includes the intellectual and intangible cultural heritage, practices and knowledge systems of traditional communities, including indigenous and local communities (traditional knowledge in a general sense or *lato sensu*). In other words, traditional knowledge in a general sense embraces the content of knowledge itself as well as traditional cultural expressions, including distinctive signs and symbols associated with traditional knowledge.” As the same document says TK can be found in a wide variety of contexts, including agricultural knowledge; scientific knowledge; technical knowledge; ecological knowledge; medicinal knowledge, including related medicines and remedies; biodiversity-related knowledge, etc.

The Convention on Biological Diversity (CBD) 1992 indirectly describes traditional knowledge as “knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity” (CBD Article 8(j)). The definition does not make any specific reference to TM, but the expressions knowledge, innovations and practices may include TM.

As per the draft legal text being considered by the Inter-Governmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore of WIPO (IGC), Traditional Knowledge refers to knowledge originating from indigenous [peoples], local communities and/or [other beneficiaries] that may be dynamic and evolving and is the result of intellectual activity, experiences, spiritual means, or insights in or from a traditional context, which may be connected to land and environment, including know-how, skills, innovations, practices, teaching, or learning.¹⁵ However, there has not yet been a consensus on the draft text, particularly on the terms within square brackets. What is crucial in this definition is that TK is developed in a traditional way as different from laboratory-based research (James:2019). WIPO explains that ‘traditional’ in the context of traditional knowledge means that the same is created in a manner that reflects community traditions and does not necessarily mean ‘old’ but is rather related to how the knowledge is created (WIPO:2015).

As regards, ‘traditional medicine’, there is not so much confusion as in the case of TK. World Health Organisation (WHO) defines “traditional medicine” as “the sum total of the knowledge, skill, 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 illness.”; it includes diverse health practices, approaches, knowledge and beliefs incorporating plant, animal, and/or mineral-based medicines, spiritual therapies, manual techniques and exercises applied

singularly or in combination to maintain well-being, as well as to treat, diagnose or prevent illness.”¹⁶ This broadly covers almost all medicinal knowledge which are outside the purview of modern medicine, though is not an ideal definition from an Indian perspective since the ISMs are clubbed with ‘non-explicable’ practices. Correa includes within the scope of TM all “knowledge concerning medicines and their use (appropriate dosage, particular forms of administration, etc.), as well as the procedures and rituals applied by healers as part of their traditional healing methods.” (Correa: 2001)

Misappropriation of TK: Cases

For long, TM and TK existed without any specific legal protection for them. But the growth of the modern pharmaceutical industry and its search for new drugs for various diseases has led the pharma industry to mine the rich knowledge source of TM. Many lifted certain TM medicines as such and applied for patents in western countries and some segregated the molecule that gave the therapeutic effect in TM and applied for a patent. This was done without seeking any prior informed consent (PIC) of the people who had conserved, preserved and nurtured that knowledge for centuries or sharing any benefits arising out of the commercial utilization of that knowledge. This process which involved the lifting of biological material also is referred to as biopiracy. Some of the important cases of such biopiracy which drew international attention are mentioned below.

The first case that received global attention for the misappropriation of TMK was that of turmeric (*Curcuma longa*). The University of Mississippi Medical Centre was granted patent number 540,1504 by the United States Patent and Trademark Office (US PTO) on 28 March 1995 against an application filed on 28 December 1993, which had six claims covering the use of turmeric powder and its administration, both oral and topical, for wound healing, i.e. to heal surgical wounds and ulcers. The ‘inventors’ were two researchers, Soman K. Das and Harihar Kohli, two persons of Indian origin, of the Centre. The news about the patent led to

much agitation in India and the Indian Council of Scientific and Industrial Research (CSIR) fought the case in the USPTO. The CSIR argued that turmeric was a native Indian plant and had been used for centuries by its people for wound healing, and consequently lacked the “novelty” criterion required for patenting. It had to hire a US patent lawyer to fight the case and spend about USD 15,000, apart from the cost involved in engaging a law firm in India to assist the US attorney, which it supported with 32 citations of documents ranging from scientific publications to books on home remedies and ancient Ayurvedic texts on Indian systems of medicine.¹⁷ The US PTO revoked the patent granted in 1995 on 13 August 1997, after a gap of two years. This was the first time India could get a patent on Indian TM revoked in a foreign jurisdiction. An earlier attempt to revoke patents on neem (*Azadirachta indica*) in the US was not successful since they related to novel processes for increasing the useful life of azadirachtin, neem’s active ingredient.¹⁸

There are attempts in other parts of the world to patent inventions based on TK or medicinal plants as such. Conrad Gorinsky’s patents in the 1980s on Cunaniol in the US and Rupununine in the UK are allegedly based on the TMK of the Wapishana tribe of Brazil and Guyana. Cunaniol was from Barbasco (*Clibadium Sylvestre*) bush, and the patent claim was for its properties as a stimulant to the nervous system that could unblock arteries and temporarily stop the human heart without damaging it. Rupununine was a compound from Tipir, the nut of the Greenheart tree (*Chlorocardium rodiei*). Tipir is used by the tribe as an anti-infection agent. However, before the legal challenges materialised, the patents lapsed.¹⁹

In 1986, Loren Millers, an American scientist patented Ayahuasca, a vine in the Amazon rain forest. Plant patent number 5,751 dated 17 June 1986 claimed rights over Da Vine allegedly a new variety of *Banisteriopsis caapi*. Traditional healers of the Amazon tribes use this plant to make a paste named *Ayahuasca*, which is used for healing.²⁰ Though the US PTO on a petition by the Centre for International Environmental Law

(CIEL)²¹ cancelled the patent in 1999 on the ground of lack of novelty, later in January 2001 it reversed that decision. The patent finally lapsed on 17 June 2003.²²

US Plant Patent No. 5,900,240 granted on 4 May 1999 is for the use of an edible composition comprising a mixture of two or more herbs consisting of *Syzygium cumini* (Jamun), *Gymnema sylvestre* (Gurmar) *Momordica charantia* (Bitter gourd) and *Solanum melongena* (Eggplant), a combination of herbal composition, as hypoglycaemic (anti-diabetic) agents.

US Patent No. 6,673,377 granted on 6 January 2004 to Cheil Jedang Corporation, Seoul, South Korea is for an extract from Kwao Krua, a Thai herb, for its property of enhancement of male sexual performance²³

US Patent No. 7,556,830 B2 dated 7 July 2009 is for a medicinal herbal composition for treating HIV and other infections extracted from 14 Kenyan plants including the root of *abyssinica* and *Clutia robusta*. The patent application refers to the use of plants by ancient societies for the treatment of infections. It also gave a list of 8 previous US patents linked to the use of plants for immunodeficiency cases. This included two (No. 5,837,257 and No. 5,178,865) that disclosed the use of Chinese herbal medicine.²⁴

There is any number of herbal patents granted in other countries based on TMK. The application for patent No. 5,900,240 on a herbal composition comprising a mixture of at least two herbs of *Syzygium cumini*, *Gymnema sylvestre*, *Momordica charantia* and *Solanum melongena* alone lists 40 patent citations in the field, as may be seen in Tables 1 and 2.

Table 1: Patent Citations on US Patent No. 5900240 on Herbal Compositions and Their Use as Hypoglycemic Agents

S No.	Publication number	Priority date	Assignee	Title
01	US6162438A	24.06.1999	Chromak Research, Inc.	Herbal compositions and their use as agents for control of hypertension, hypercholesterolemia and hyperlipidemia
02	WIPO PCT (WO) 2001005416A1	15.7.1999	Pushpa Khanna	Oil from momordica charantia l., its method of preparation and uses
03	US6274176B1	01.07.1999	Chromak Research, Inc.	Herbal compositions and their use as anti-inflammatory agents for alleviation of arthritis and gout
04	WO2003020293A1	05.9.2001	Xiaoping Zhu	Health-care product for regulating blood glucose and its preparation method
05	US6572897B1	03.7.2002	Vitacoŝt. Com, Inc.	Insulin sensitivity maintenance and blood sugar level maintenance formulation for the prevention and treatment of diabetes
06	Spain (ES)2193887A1	23.4.2002	Navajas Juan Carlos Agreda	Herbal product to be administered to diabetic individuals and the production method thereof
07	US20040151783A1	12.11.2002	Chatterji Arun K.	Therapeutic compositions

Table 1 continued...

Table 1 continued....

08	WO2005009351A2	17.7.2003	Santé International, Inc.	Dietary supplement for promoting control of blood-sugar levels and associated pathology in type 2 diabetics
09	KR100492821B1	23.5.2002	Naturo BiotechCo. Ltd.	Composition for improving hyperglycemia and inhibiting development of diabetes induced complication containing cuminaldehyde
10	US6949261B2	12.11.2002	Ayurvedic-Life International, Llc	Compositions for diabetes treatment and prophylaxis
11	JP2005343832A	03.5.2004	Nth:Kk	Ingredient contained in myaceae vegetable and application of the same
12	US20080206372A1	23.4.2002	Juan Carlos Agreda Navajas	Herbal product to be administered to diabetic people and process to obtain it
13	US20080241281A1	29.3.2007	Texas Tech University System	Compositions & methods for activation and inhibition of Staphylococcus aureus biofilm development

Table 1 continued....

Table 1 continued...

13	WO2009098702A2	06.02.2008	Sadashiv Damle Ramchandra	A hypoglycemic herbal extract composition for reducing blood sugar levels in mammals
14	US8071844B1	13.9.2007	Nutritional Health Institute Laboratories, Llc	Cultivated momordica species and extract thereof
15	US20140271924A1	15.3.2013	New Chapter, Inc.	Composition and method for blood sugar modulation

Source: <https://patents.google.com/patent/US5900240A/en>

Table 2: Additional Citations on US Patent No. 5900240

S.No.	Patent No.	Date of Priority	Title
01	US5900240A	04.5.1999	Herbal compositions and their use as hypoglycemic agents
02	Japan (JP)4442742B2	31.3. 2010	Composition for enhancing insulin activity and method thereof
03	China (CN)103238897B	04.6.2014	Composite plant solid drink suitable for diabetic patients
04	US6652891B2	25.11.2003	Co-enzyme Q10 dietary supplement
05	CN104026446A	10.9.2014	Nutritional meal replacement powder suitable for crowd with hyperglycemia and preparation method thereof
06	US6280776B1	28.8.2001	A composition comprising Panax pseudo ginseng and Eucommiae ulmoides

Table 2 continued...

Table 2 continued....

07	CN106360310A	01.02.2017	Composition for dropping after meal blood sugar and application thereof
08	CN109221898A	18.1.2019	A kind of grain dust and its preparation method and application containing xylo-oligosaccharide
09	JP2008094754A	24.4.2008	Nutrient composition for diabetes or blood sugar control
10	Russia (RU)2661622C1	17.7.2018	Solid phase composition of natural bioactive ingredients for correction of metabolic disturbances in diabetes mellitus type ii
11	CN102065874A	18.5.2011	Compositions for reducing blood glucose level and uses thereof
12	US5250301A	05.10.1993	Method for treating digestive organ disorders
13	CN1143681C	31.3.2004	Medicinal composition for diabetes
14	JP2003238442A	27.8.2003	Composition for eyes health
15	US20100323031A1	23.12.2010	Synergistic combination to enhance blood glucose and insulin metabolism
16	Korea (KR)100653460B1	07.12.2006	Antidiabetic composition containing the extracts of mulberry leaves and fenugreek seed
17	KR101989739B1	14.6.2019	Composition for preventing or treating diabetes mellitus comprising Rorippa globosa extracts
18	KR100522532B1	20.10.2005	Composition for hypoglycemic effect comprising paecilomyces japonica and Momordica charantia

Table 2 continued....

Table 2 continued...

19	US5846544A	08.12.1998	Composition and method for reducing blood sugar levels in diabetic humans
20	WO2005072064A2	11.8.2005	A preparation, process and regenerative method and technique for prevention, treatment and glyceemic control of diabetes Mellitus
21	CN105641674A	08.6.2016	Compound nanometer preparation for treating diabetes mellitus type 2 and preparation method thereof
22	US8703213B2	22.4.2014	Anti-diabetic composition containing a plant extract of <i>Englerina lecardii</i>
23	JP20090623 48A	26.3.2009	Hypoglycaemic action and blood sugar level elevation-suppressive action by seed ingredient of kenafs (kenaf and roselle)
24	KR100894029B1	22.4.2009	The ginseng flower composition, that prevention and remedy cure to sugar diabetes

Source: <https://patents.google.com/patent/US5900240A/en>

Some of the citations like US20080241281A1 and US8071844B1 may not pertain to TMK.

Such a large number of patent applications concerning one TMK in different countries, namely, China, Spain, Japan, the Republic of Korea, Russia, USA and the WIPO Patent Cooperation Treaty, indicates the extent to which patents happen in the TM area. There are no documents available on the US PTO site to show these patenting activities were based on any PIC or ABS agreement and there is no disclosure of origin of BR or TK.

Cases happened in the Southern hemisphere also. The *Hoodia pilifera* case in South Africa is one such. It is a cactus plant

used by the San tribe for centuries to stave off hunger and thirst during hunting trips in the desert. In 1996, researchers from the South African Council of Scientific and Industrial Research (SACSIR) isolated the hunger-suppressing component from the plant, which they named P57 and patented. The SACSIR then licensed a pharmaceutical company to develop and market a natural appetite suppressant based on P57. While the SACSIR got the knowledge from the San people, they were not involved in the licence agreement with the pharma company. The San people then agitated and represented and finally in 2002, the SACSIR agreed to share the profit with the TK holders, namely, the San nation (Arihan and Anr.2007).

These are some illustrative cases only which show how misappropriation and patenting of TMK happen when adequate precautions are not taken by the holders of the knowledge.

International Discussions on TK protection

The cases of misappropriation of TMK have generated discussions in various international fora on ways to protect against such misappropriation. The discussions were not exclusively on TM but TK in general, though medicinal knowledge formed a major chunk of global TK. The Convention on Biological Diversity (CBD) (1992) is the first move towards international law on TK protection. It functions as a framework instrument which requires supplementary documents to be implemented. The Convention established the principle that all biological resources and associated TK fall within the sovereign rights of the country in which the same are situated. That would mean any access or appropriation of the same without permission of the designated authority is in contravention of the CBD. It also laid down the general principles for accessing and exploiting the biological resources and associated TK but has not established an IPR-like system. As one of the steps in elaborating on the CBD, working groups and meetings of the Conference of the Parties (COP) managed to produce two instruments: The Bonn Guidelines (2002) and the Nagoya Protocol (2010).

The Bonn Guidelines on access to genetic resources and the fair and equitable sharing of the benefits arising from their utilization (2002) are important steps in elucidating the CBD. It is a voluntary system proposed to help member countries in developing legislation and contractual regimes for access to benefit sharing from the use of genetic resources and TK. Several member states, especially developing countries, and Least Developed Countries (LDCs), have used the system to establish national ABS mechanisms. The Guidelines, through Section C 16 d(ii) promoted a discussion on the requirement of disclosure of origin of source countries/ communities in procedural and substantive patent law instruments. The disclosure of origin requirement pertains to a patent application that, directly or indirectly, has used a genetic resource or TK in developing the invention. Following the inclusion of such a standard in the Bonn Guidelines, the disclosure requirement was incorporated in the (procedural) Patent Cooperation Treaty and the (substantive) Patent Law Treaty.

The Nagoya Protocol, adopted at the 10th Conference of Parties (COP), a mechanism established by the CBD, in 2010 and which entered into force in 2014, expands upon the CBD provisions establishing a substantive regime governing Access and Benefit-Sharing (ABS). The purpose of the Protocol is to provide legal certainty and clarity in implementing the CBD's third objective, namely, access to genetic resources and the fair and equitable sharing of benefits arising from their utilization.

The TRIPS Agreement (1994) is the most important international treaty on IPRs, as stated above. The relationship between CBD and TRIPS is an issue under discussion in the TRIPS Council. Three views have been taken by Members on the issue. One view is that there is no conflict between the two and it is for national governments to implement the two in a mutually supportive manner. A second view is that there is inherent conflict and the TRIPS Agreement be amended to exclude from patentability living organisms, including plants, animals and

microorganisms. A third view is that while there may not be any conflict, there is considerable overlap and to remove the same amendments be made to the TRIPS Agreement to provide that a patent application if it relates to biological resources or TK should (i) disclose the source and country of origin of the biological resource and the traditional knowledge used in the invention; (ii) provide evidence of prior informed consent through approval of authorities under the relevant national regimes; and (iii) evidence of fair and equitable benefit-sharing under the relevant national regimes. (James et al:2021). India's stand has been that the Agreement may require an amendment to prevent misappropriation of its TK. This has been well articulated in the statement of Shri Ramakrishna Hegde, the then Minister of Commerce at the second WTO Ministerial (1998):

Indeed, the issue of development of proprietary patents by enterprises based on the traditional knowledge of indigenous communities, nurtured through generations, without obtaining prior informed consent or without coming to any agreement on benefit sharing, have been viewed as iniquitous practices by countries such as India, which are storehouses of such indigenous knowledge. A situation, where indigenous biotechnology, developed over the ages in countries such as India, is being used without any flow back of benefits from patentees to original developers calls for amendments in the TRIPS Agreement.²⁵

He went on to state that the TRIPS Agreement is tilted against holders of indigenous know-how, mainly based in developing countries. The protection of TK holders is likely to lead to considerable gains for traditional health practices (Dhar: 2017). However, as of date, there is no amendment to the TRIPS Agreement to protect TK as provided in the CBD or to grant any special treatment for TK in patenting. This, effectively, leaves TMK in the realm of knowledge commons.

Another forum where discussions on the protection of TMK take place is IGC of the WIPO. This body was established in 2000

and currently discusses three draft legal texts on the protection of TK, Traditional Cultural Expressions and Genetic Resources. Various groups of like-minded countries emerged during the process of the IGC negotiations. A general classification of these groups shows that most developing countries (especially those with a high intensity of biodiversity and indigenous communities) strongly advocate the international protection of TK while most developed countries prefer to maintain the *status quo* (James, *et al.* 2021). The various groups of like-minded countries include, among others, the Asian Group, the African Group, GRULAC (Latin American and Caribbean Group), Group B (US, Japan, New Zealand, EU, and Australia), the Central European and the Baltic States, and Central Asian and East European Countries. As can be observed from negotiation texts, developing countries with significant biodiversity resources and traditional knowledge, and those in which a considerable number of local communities reside (especially Brazil, India, Peru, and some African countries) are strong demanders of TK protection. The following statement describes the state of play and the motivating factors of the two groups:

*Broadly, during negotiations, two groups of countries have emerged—Group A comprising developing countries like the African group, Asian group and GRULAC, where the TK that exists today is largely concentrated, and Group B comprising of developed countries like EU, Japan, the USA and Canada, which are afraid of losing the free access to GRs, TK and TCE that they have been used to through the colonial period over 200 years. China, which stands apart, has held positions similar to countries like India which is widely/publicly available and has commercial value that is open to misappropriation.*²⁶

India's stand in the IGC has been against misappropriation through IPRs of TMK. In the IGC like in other international fora, the discussions are focussed on this aspect only and not on positive IPR protection such as any kind of patents.

The UN Declaration on the Rights of Indigenous Peoples makes a clear commitment to protecting the IP of the indigenous people on their traditional knowledge; it can be done as collective property unlike personal property as envisaged in the IPR treaties. UNESCO looks at TK from a cultural perspective. Its Local and Indigenous Knowledge Systems programme (LINKS) promotes local and indigenous knowledge and its inclusion in global climate science and policy processes. It, of course, stresses the need to enhance the intergenerational transmission of indigenous knowledge, as a complement to mainstream education. It has also initiated steps to bring indigenous language and knowledge into school curricula and to move learning back into the community, thus reaffirming the status of elders as knowledge holders.²⁷ However, TMK, as such, does not figure in the UNESCO agenda yet. Some of the strands that emerged in the international discussions on TK which have salience for TM are the following:

One, TMK deserves to be given due recognition as a genre of humanity's knowledge treasure. It has an important role in innovations. The communities who preserved the knowledge deserve to be compensated for the use of the knowledge by others.

Second, TK is not bereft of innovations. Advances do take place in TK, but they are in a traditional way and not in the methods of modern science. In fact, TM has made tremendous progress in innovative drug development. As per a report, 3,563 extracts, 64,715 compositions, 5,000 single compounds and 130 kinds of Traditional Chinese Medicine (TCM) related chemical drugs have been developed (Pan et al. 2014).

At the same time, there is a trend towards identifying 'indigenous people' as the source of TK. This is a term that was developed in the context of the colonization of the Americas and Australasia to distinguish the colonial settlers from the local or indigenous people (James:2022). Applying the term in Asian and African countries creates an artificial division among the local people. It will make systems of medicine

like Chinese Medicine, Ayurveda, and so on outliers. On the one hand, modern science does not accept these medicine systems as modern and on the other hand in the discussions on protecting TK, they are equated with the mostly oral knowledge of the colonised people of the Americas and Australia.

TM Protection in Select Countries and in India

Many countries have accorded varying levels of protection on TK. In line with the international negotiations in WIPO and the CBD, most national laws regulate the access and benefit-sharing regimes.

Most Latin American countries like Brazil, Costa Rica, Peru and Venezuela, which have sizable populations of indigenous people, have legislations which recognise the indigenous communities' rights over their TK; that knowledge cannot be appropriated and used commercially by third parties without their consent. The laws cover plant-based medicines also. The four member states of the Andean Community, namely, Colombia, Ecuador, Peru and Bolivia, have established a system that requires that for an invention that involves the use of the TK of a local community certified written consent from the said community must be obtained. In the absence of such consent, no patent will be granted. In some countries, like Costa Rica, the right is automatic and does not require any registration. Ecuador provides a registration system for ancestral knowledge. Chile, Peru, Mexico and others in South America also follow this pattern of protection of biological resources and associated TK including the knowledge of the indigenous communities. Brazil even prescribes by law the quantum of benefit sharing on products derived from Brazilian biodiversity.

South Africa like India has provided the source of origin disclosure requirement for TK-based inventions for getting patents. As per the Patents (Amendment) Act 2005, every patent applicant has to submit a statement whether or not the invention is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use and also proof of authority to use the same.²⁸

In Asia, the Philippines has the Indigenous Peoples Rights Act, 1997 extending protection to the “community intellectual property rights” of indigenous peoples, including their TM and health practices and indigenous knowledge systems and practices. Among Asian countries, Thailand has a long tradition of Traditional Medicinal Knowledge. It has a vast resource of medicinal plants, according to some, about 10,000 plant varieties. Thailand enacted two legislations that relate to TK in 1999, the first one is the Plant Varieties Protection Act, which, *inter alia*, protects the local knowledge of farmers relating to plant breeding and the second, the Protection and Promotion of Thai Traditional Medicine Intelligence Act, which is intended to protect the traditional medicine knowledge and access to TK and biological resources in herbal medicine. The Plant Varieties law has provisions relating to access and benefit sharing in the case of the collection of wild plant varieties for commercial purposes. However, there has been criticism that both laws provide neither a functional system nor an effective enforcement mechanism (Meeklam 2015).

China follows a slightly different path. It has a robust and well-documented Traditional Chinese Medicine system. China also, like India, holds the view that all people of China are indigenous and there are no separate indigenous communities (James 2022). *Ipsa facto*, their laws are not to protect the traditional knowledge of any particular community but of all people of China and that applies to Traditional Chinese Medicine.

The Patent Law of the People’s Republic of China (as amended up to the decision of October 17, 2020²⁹ regarding the Revision of the Patent law of the People’s Republic of China) and the Regulations on the Protection of Varieties of Chinese Traditional Medicine can be described as the main provisions on the protection of TK in China. The Patents Law provides exclusive rights to the patentee. It provides positive protection with the major objective of the promotion of innovation. The scope of the Law includes the product (a new pharmaceutical composition and preparation thereof, an effective ingredient extracted/

separated from traditional medicine, effective parts, and preparation thereof, a new preparation of changing the administration route, etc.), method (preparation method of the products mentioned, new or improved technology of production, etc) and Use (new indication of medicine, first medical use, the second use of the known medicine, etc.) While the law provides no express access-related provisions, conditions on TK protection are based on novelty, inventiveness, and utility. The scope of rights extends the rights to prevent third parties not having the right holders' consent from making, using, offering for sale, selling or importing the patented invention; and bringing litigation when infringement occurs; Regulations on the Protection of Varieties of Chinese Traditional Medicine is limited to protecting the production of the protected species and Manufacturing without permission. The rights holders under the Regulations on the Protection of Varieties of Chinese Traditional Medicine are only the manufacturing companies.

China has a separate category of Chinese patent medicines which generally consist of herbs extracted and converted into black pills, though there can be other forms like dripping pills, liquids, syrups, powders, granules, instant teas, and capsules, they are not patented in the traditional sense of the word. No one has exclusive rights to the formula. Instead, "patent" refers to the standardization of the formula. All Chinese patent medicines of the same name have the same ingredients and are manufactured by the PRC's Pharmacopoeia's monograph on that particular formula.

US Patent law does not have any specific provision against the grant of patents on TK. While TMK is existing knowledge, the definition of novelty before the AIA 2013 did not consider oral knowledge and use outside the US as prior knowledge and therefore patenting on TMK was easier. Even after AIA 2013, the US is quite liberal in the grant of patents on innovations based on TM. Many Indian companies like Muniyal Ayurveda, Manipal, Dabur India, Sami Labs and even CSIR have obtained patents in the US. The subject matters generally include herbal

compositions, herbo-mineral products, plant extracts, phytochemicals, herbal soft drinks, nutraceuticals and so on. The patent law provisions that affect TM in European countries and Canada are rather similar.

In India before the advent of Modern medicine in the form of Western or English medicine on the subcontinent, people were resorting to different kinds of medical treatments. These can be broadly divided into two: (i) the documented and organised systems, and (ii) undocumented and largely unorganised practices. Ayurveda, Siddha and Unani are the three famous Indian Systems of Medicine (ISMs) which are documented knowledge and based on theoretical principles and experiments. They are scientifically systematised knowledge which has authoritative books, explaining the principles, the rationale, the ways of diagnostics, the medicines including their dosage forms to be used and other ancillary matters. Folk and tribal medicinal practices mostly are undocumented and vary across the country. In recent years, there have been attempts at documenting this knowledge too, but even when documented, they would differ from the ISMs fundamentally since they lack scientific theoretical premises of the systems (James: 2015).

There are two kinds of IP protection, namely, defensive, and positive. Defensive protection does not grant any positive rights to the holder but prevents outsiders from acquiring IP rights over products and processes. This is proposed in the case of TK. In that case preparation of a searchable database like the Traditional Knowledge Digital Library (TKDL) is considered a means to prevent others from obtaining patents on the knowledge or information contained in that database, since that would be considered prior art by the patent examiner while assessing the patentability of an invention. In this, there are no positive gains for the knowledge creator or holder.

Positive protection, on the other hand, grants rights to the creators or holders. The IPRs are meant for that even though they are granting negative rights only. For example, a patent is a right to prevent third

parties from making, using or importing the patented product or process (Article 28, TRIPS Agreement). The International IP regime does not make it mandatory for the patentee to make or sell the product. Be that as it may, patent protection is what is sought by many who argue for protecting TM through IPRs.

Indian IP Laws and Traditional Medicine³⁰

National IP laws are offshoots of international law. India's relations with international law are clearly defined in Article 51 of the Constitution, which puts the onus on fostering respect for international law and treaty obligations in the dealings of organised peoples with one another, on the State. While the Constitution does not specify intellectual property rights, the Seventh Schedule includes Patents, inventions and designs, copyright, trademark and merchandise marks (Item 49 of List I) under the legislative domain of the Union thereby implicitly recognising IPRs.

Although India has had IP protection legislation since the second half of the 19 century and Indian Traditional Medicines (ITMs) were the predominant health care systems in most parts of the country and, in some areas, the only available systems, there were no special provisions in the IP laws for extending protection to the systems. Even in the princely states, like Mysore and Travancore, where ISMs were given special encouragement, this was the situation. In the erstwhile Travancore, which on India's Independence got merged with certain other parts to form the state of Kerala, a college for Ayurvedic education was opened in 1889. But no effort was made to evolve a policy or law for protecting the IP quotient of the system. The ISM system institutions were also encouraging research and development, though within the bounds of the ancient texts. Perhaps because of the Indian traditional perception of knowledge as a common good, rather than private property, the practitioners and administrators did not think of encasing them within IP laws. Another reason could be the basic approach of the traditional practitioners and students to an unquestioning acceptance of the standard

texts in the ISMs. This approach continued even after the Independence and well into the 1990s, during which most of the IP laws were either amended or recast. A change in the policy approach came with the advent of the TRIPS Agreement and attempts in the West to misappropriate the knowledge of the Indian Systems of Medicine through patenting and other IP measures. When amendments and recasting of India's IP laws as a response to the new international regime were taken up, this aspect was also given considerable thought. Consequently, certain provisions were incorporated in many of them to extend better protection to the Indian Systems of Medicine and also other traditional medicinal knowledge of the country. In the following paragraphs, we may take a look at the availability of protection for traditional medicine in the various IP laws of India, as they exist today.

The current Patents Act is of 1970, amended in 2005. This Act, originally, excluded medicines from the purview of product patents keeping in view the public interest and to ensure the availability of affordable medicine to the large public who were rather poor. As part of making the law compatible with the obligations under the TRIPS Agreement, three amendments were carried out in the Act in the years 1999, 2002 and 2005. The 2002 amendment, *inter alia*, provided that “an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of a traditionally known component or components” is not an invention within the meaning of the Act.³¹ Since TMK forms part of TK, this provision ensures that no one can patent an existing knowledge or formulation in the field of Indian Systems of Medicine (ISMs), such as the medicinal properties of turmeric, which is recorded in ancient Ayurvedic texts and thus is TK.

The Act also provides the following criterion as a ground for opposition, both before grant and after the grant, namely, “that the invention so far as claimed in any claim of the complete specification is anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere.”³²

This provision extends the scope of protection for traditional medicinal knowledge by including within its purview the oral knowledge also, although most of the knowledge in the field of Indian systems of medicine is documented and available in classical texts. This is also a ground for the revocation of a patent.³³ Thus, the Patents Act prevents the misappropriation of TMK.

The provisions in the Patents Act reflect the policy angle that existing knowledge in traditional medicine deserves to be protected from misappropriation while extending patent protection to new ‘inventions’ in that field. At the same time, the Act does not stand in the way of patenting new inventions in the field of Indian Systems of Medicine since it does not distinguish between technologies when it comes to defining the invention which could be a new product or process involving an inventive step and capable of industrial application.³⁴ The amendments to the Patents Act in 2005 extended product patents to pharmaceuticals and food items. Therefore, new formulations and processes in Ayurveda, Siddha and Unani could be patented, if they meet the criteria for patentability. In fact, even earlier, new processes in these systems could be patented as could be seen from the process patent for Jeevani, an Ayurvedic drug developed by the Tropical Botanical Garden and Research Institute, Thiruvananthapuram which became a celebrated case in benefit sharing in traditional knowledge.³⁵

There are many patents for various Ayurvedic, Siddha and Unani formulations. Most of them are for processes. Some such patents (up to 2015) are listed below to give an idea about the patenting activity in this area (James:2015).

- A process for preparing Ayurvedic anti-snake venom.³⁶
- An Ayurvedic composition for joining fractured bone.³⁷
- Herbal Ayurvedic composition for the treatment of psoriasis.³⁸
- A process for preparing novel Unani composition Jigirina for the treatment of viral hepatitis and jaundice.³⁹

- A herbal composition for controlling blood sugar levels and process for preparing the same.⁴⁰
- A herbal composition against bronchial asthma and process for preparation thereof.⁴¹
- An antiulcer synergistic herbal formulation.⁴²
- A herbal composition for the treatment of diabetes.⁴³
- Ayurvedic antiretroviral composition for the treatment of acquired Immuno Deficiency syndrome.⁴⁴
- An Ayurvedic composition for oral consumption in the treatment of heart diseases and hypertension.⁴⁵

While the exact number of patents on TMK in India needs to be verified, calculations based on various norms have been presented in the past. In a reply to the Lok Sabha in August 2013, it was stated that as of 31 March 2013, 86 applications were filed by foreign entities and 523 applications were filed by Indian entities for grant of patents for products, formulation, compositions & processes in the field related to traditional ayurvedic medicine, medicinal plants and herbal based formulations. Of these, as of that date, 26 patents have been granted to foreign entities and 93 patents to Indian entities.⁴⁶ It was stated in reply to Lok Sabha starred question No. 83 on 22 July 2022 that the number of patent applications filed and the number of granted patents having Ayurveda-related proprietary knowledge during the years from 2019 to 2022 were 861 and 86 respectively.⁴⁷ However, the number of patents which have reference to Ayush systems or medicinal plants is very high. A ‘complete specification’-based keyword reference search of the Indian patent database⁴⁸ (on 6 October 2022) yielded the results in Table 3.

Table 3: References to plants and herbs in Indian Patent Applications

Keyword	No. of references
Plant	24,463
Root	8,405
Herbal	1,543
Herb	765
Bitter melon	1,835
Bitter gourd	1,475
Cardamom	805
Ginger	704
Turmeric	451
Liquorice	391
Cumin	218
Amla	82
Gotu kola	76
Boswellia	73
Brahmi	44
Ashwagandha	17
Haritaki	14
Bibitaki	04

Source: Author's compilation.

These references do not mean that they are all patented but in the prior art or other documents such references can occur. At the same time, the references can throw light on patenting in the field of Indian TM. For example, application No. 202221043410 dated 22 July 2022 by Pornima Shamrao Patil published on 12 August 2022 is for an invention titled “Curcumin Loaded Solid Lipid Nanoparticles for Anti-Inflammatory Use”. As per the application, the field of invention is chemical and the IPC classifications covered are A61K0009510000, A61K0031120000, A61K0009500000, A61K0047360000, A61K0009160000⁴⁹. The

inventions relate to synthesising Curcumin loaded Chitosan/ glyceryl monooleate (GMO) Nanoparticles (Cu-loaded chitosan nanoparticles) for controlled release to target anti-inflammatory use and the principal claim is for “a herbal nano formulation comprising the synthesise of Curcumin loaded Chitosan/GMO Nanoparticles (Cu-loaded chitosan nanoparticles) for controlled release in order to target anti-inflammatory use.” While most patent applications relating to Ayush are for processes, there are also applications for devices such as a comprehensive tool for therapeutic induction of Enema and Systems, Ksharsutra – a medicated thread for ano-rectal diseases, and methods for automated manufacturing of medicated threads.⁵⁰

The Trademarks Act, of 1999 replaced the Trade and Merchandise Marks Act, of 1958. Trademarks are distinctive signs, logos, marks and so on used on goods and services by firms in trade and commerce. The Act does not have any specific provision for the protection of traditional medicine. However, like in the case of other systems of medicine, the provisions of the Act could be used for protecting the brands and marks of the producers of traditional medicines. Many Ayurvedic, Siddha and Unani pharmaceutical firms are protecting their products through this route. We have trade marks for Dabur, Baidyanath, Zandu, Nagarjuna, Himalaya and so many others from the traditional medicine manufacturing sector. The 1999 Act also provides for trademarks in the service sector. This helps hospitals and healthcare centres in the field of Indian Systems of Medicine also to obtain trademarks. Certification trademarks are for attesting to certain specified quality standards. These marks can be effectively used in the pharmaceutical products of Indian Systems of Medicine. Similarly, collective trademarks can be obtained by a group or cluster of pharma firms. These provisions in the new Trade Mark Act are quite Indian Systems of Medicine friendly and reflect the positive approach of the government towards them.

The Geographical Indications of Goods (Registration and Protection) Act 1999 provides for the protection of geographical

indications which identify goods as originating or manufactured in the territory of the country, or a region of locality, where a given quality, reputation or other characteristics of such goods is essentially attributable to its geographical origin and in cases where such goods are manufactured goods one of the activities of either the production or of processing or preparation of the goods concerned takes place in such territory, region or locality.⁵¹ The inclusion of manufactured goods within the ambit of the geographical indications enables indicators such as names of traditional medicinal products which have quality or reputation or other characteristics that could be adduced to a geographical area to get protection for that indication. Geographical Indication serves as a certificate of geo-authenticity, a concept which is of utmost importance in TM (Brinckmann:2014). Crude herbs prescribed in classical Ayurveda texts are geo-specific since the qualities may differ when collected or cultivated in different geography. There is a possibility of some traditional medicine products acquiring special qualities which are linked to the region where they are manufactured. Some examples of products with registered geographical indications which have TM applications are Navara (*Shashtikalshali*) rice, Aleppy and Coorg Cardamom (*Suksma ela*), Ganjam kewda flower (*Ketakipushpa*), Kashmir Saffron (*Kumkumam*), Sangli turmeric, Sirumalai hill banana, Virupakshi hill banana, and Marayoor jaggery.⁵²

The Designs Act, of 2000 protects the external features of an article. This enables manufacturers in the area of Indian systems of medicine to protect the designs they used for the containers for dispensing medicines. However, the Act does not extend any protection to the actual contents.

The Copyright Act, of 1957 protects expressions and not ideas or products. Therefore, traditional medicinal knowledge does not come under its protection. However, copyright protection is available to textbooks and other writings on traditional medicine. Since a good number of new books and publications on ITM, including research papers, in various languages are published every year, both in India and abroad,

copyright protection is valuable. Many even make documentaries and recordings on tribal medicine which also get IPR protection through the copyright route, though the knowledge recorded or depicted therein is not protected.

The Protection of Plant Varieties and Farmers' Rights Act (PPV&FR Act), 2001 is of value to TM. The Act provides for the registration of new and extant varieties. Extant varieties have to conform to the criteria of distinctiveness, uniformity and stability for getting registered under the Act⁵³. Farmer groups and communities can register such varieties. An attraction of the Act is that it provides for benefit sharing on the registered varieties including the new varieties registered by breeders. The quantum in each case is to be decided by the Plant Variety and Farmers' Rights Authority (PVFR&A) and the benefits will proceed to the National Gene Fund. A farmer who is engaged in the conservation of genetic resources of land races and wild relatives of economic plants and their improvement through selection and preservation is entitled to recognition and reward from the Gene Fund.⁵⁴ The Act also provides that any local community can stake any claim attributable to the contribution of that community in the evolution of any variety. Use of any registered variety for conducting research or experiment is exempted⁵⁵, thus allowing traditional medicine practitioners to experiment with both new and extant varieties of plants since most of the ISM drugs are plant-based. Another provision of relevance to traditional medicine is the one relating to exclusion of certain varieties from registration where prevention of commercial exploitation of such variety is necessary to protect, *inter alia*, health.⁵⁶

Apart from purely IP regulations, other related laws also can be availed of for obtaining protection for certain aspects of ISMs in various ways.

The Biological Diversity Act, 2002 (BDA) was enacted to provide for the conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out

of the use of biological resources, knowledge and matters connected therewith or incidental thereto.⁵⁷ All these objectives are salient for the protection of traditional medicine systems. These systems are dependent on biological resources, which are the raw materials for the drugs that they use. The quality of the medicines also may vary dependent on the place from which and time at which the biological resources are collected. The ITM industry, however, has concerns about the provisions since the law regulates their access to biological resources. Further, TMK will also come within the purview of the Act, because of the close interrelationship between that knowledge and the biological resources.⁵⁸

While regulating access to the biological resources available in India, the Act also regulates access to knowledge associated with biological resources for research or commercial utilization of even bio-utilization.⁵⁹ Commercial utilization includes the use of biological resources for drugs, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, colours, extracts and so on. Of course, Indian citizens can access the resources without any specific prior approval but should give prior intimation to the State Biodiversity Board concerned. Foreigners need to take prior approval from the National Biodiversity Authority (NBA). However, before applying for any IPR, in or outside India, for any invention based on any research or information on a biological resource obtained from India, previous approval of the NBA is required by all. While granting such approvals, the NBA may impose a benefit-sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilization of such rights.⁶⁰

In sync with the BDA, the Patents Rules, 2003, in Form 1 prescribed for application for grant of a patent, requires the declaration that “the invention as disclosed in the specification uses the biological material from India and the necessary permission from the competent authority shall be submitted by me/ us before the grant of patent to me/ us.”⁶¹

The provisions in the BDA reflect the policy concerns of India which are to protect biological resources as well as traditional knowledge

including traditional medicinal knowledge. The approach is from a community perspective in that the TK systems are the common IP of the community which has developed and maintained that. In international and bilateral negotiations also, India takes this view.

The Scheduled Tribes and Other Forest Dwellers (Recognition of Forest Rights) Act, 2006 contributes to the protection, preservation, and development of traditional medicine by extending various rights to live in and exploit in a sustainable way forest resources, including the right to access to biodiversity and community right to IP and traditional knowledge related to biodiversity and cultural diversity, to the traditional forest dwellers and communities.⁶² The minor forest produces that they can access, and use include, among other things, honey and medicinal plants and herbs⁶³ which are used in various traditional medicines. Since there are large numbers of tribal and folk medicine practitioners in India, who, besides the practitioners of Indian Systems of Medicine, must access and use minor forest products, the law is a facilitative one for the traditional medicine practitioners.

The Drugs and Cosmetics Act (DCA) also reflects the general approach of the government towards traditional medicine. It has got elaborate provisions for Indian Systems of Medicine. This Act provides for the constitution of an Ayurvedic, Siddha and Unani Drugs Technical Advisory Board and for an Ayurvedic, Siddha and Unani Drugs Consultative Committee to advise the governments both at the Centre and the States on the ISM drugs.⁶⁴ It has detailed regulations regarding the manufacture for sale of ISM drugs as well as their safety and quality standards.

The D&C Act categorizes the ISM drugs into (i) classical preparations and (ii) Patent or Proprietary Medicines. Classical preparations are those drugs manufactured exclusively following the formulae described in the classical texts on Ayurveda, Siddha, and Unani systems of medicine. Patent and Proprietary medicines are those formulations, which are produced and packaged, based on the classical texts, but not included

under the classical formulations. This would include the tablets, capsules and other formats used by pharmaceutical companies to bring to the market *churnas* (powders), *asavas* and *arishtas* (liquid preparations) and so on⁶⁵. A high percentage of formulations⁶⁶ from the modern ISM industry claim protection as patent or proprietary medicine (PPM) while marketing. Patent or proprietary medicines (PPMs) are different from medicines that got patents under the Patents Act.

It must be noted that the definition of ‘patent or proprietary medicines’ in the DCA was introduced at a time when medicines could not be patented in the country under the Patents Act. Now medicines can be patented, and brand names and proprietary names can be trademarked. As observed by the Allahabad High Court, it is appropriate that the DCA be amended, and a declaration be required that the medicines are not patented under the Patents Act and the name is not a trade mark of any other person.⁶⁷

The various legislations bring out the overall positive and encouraging attitude of the government towards the development of traditional medicine. The policy is in favour of these systems making effective use of the IP and other laws of the country to protect their innovations and creativity in this vital health-related sector. At the same time, the provisions have their limitations. For example, while the Patents Act protects traditional medicine knowledge from getting misappropriated, it does not extend the positive protection that the ISMs deserve for the knowledge that has been preserved and developed traditionally. As of now, there is no comprehensive law to protect traditional knowledge, including traditional medicine, in India.

When it comes to IPR protection, the only IPR that poses challenges for Traditional Medicine is patent. In other IPRs like trademarks, designs, copyrights and so on, one does not face any distinctive difficulty. Firms engaged in the manufacture or trade of TM products and providing TM services can acquire trademarks, obtain design rights for their articles if the external features that appeal to the eye are novel and artistic,

and the literary and artistic works get copyright if the expressions are original. When it comes to patents, innovations which satisfy the criteria of novelty, inventiveness and industrial application can get patents, but existing knowledge, which is what most Traditional Medicines are, stand debarred. This is the single most important challenge: is there any way to extend patent or patent-like protection to TM? Correa who studied the subject in depth believes that not all TMK may be deemed as disclosed and lacking novelty for patent protection (Correa:2001).

National Policies and IP Protection of Traditional Medicine

India had come out with a National Health Policy in 1983. That referred to the rich and centuries-old medical heritage of the country. It suggested the necessity to initiate measures to enable the Indian Systems of Medicine to develop according to their particular geniuses. While ISMs were included within the broad policy framework, the high thrust on modern allopathic medicine to tackle the disease burden and to improve the overall health of the people of India, made the Traditional medicine sector a bit player in the health care system. Therefore, to give due prominence and attention to these systems, the government came out with a separate National Policy on Indian Systems of Medicine and Homoeopathy in 2002.⁶⁸

This Policy recognised the problem of protection of IPRs in ISMs. It observed:

Our wealth of knowledge on formulations and medicinal uses of plants available in ancient texts and treatises have been attracting foreign interest and a large number of such medicinal uses have been patented by them claiming as innovations though these are already available in the public domain and therefore cannot be patented. This has happened as such knowledge is not available in easily accessible form and in the language generally used by the patent examiners overseas. This has harmed our national interest as the process for retrieval and

*contesting patents is very costly and time consuming which we can ill-afford.*⁶⁹

To add to this, it may be remembered that traditional knowledge when shared, it is shared among those who are trusted to know their roles and responsibilities in using the knowledge and as such is not knowledge in the public domain (Tulalip Tribes: 2003). One of the objectives of the new policy was to provide full opportunity for the growth and development of the Indian Systems of Medicine and utilization of their potentiality and strength and revival of their past glory.

So far as IPRs are concerned, the Policy envisaged the following strategies:

- Protection of India's traditional medicinal knowledge would be undertaken through a progressive creation of a Digital Library for each system and eventually for uncodified knowledge leading to innovation and good health outcomes.
- *Relevant International fora would be addressed about the need for fair and equitable sharing of benefits to the custodians of the knowledge and a system of compensating the originators of such knowledge introduced.*
- *TRIPS have provided the signatory countries the freedom to choose intellectual property protection of plant varieties either under a patent regime or a sui generis system or a combination thereof. A sui generis system will be set up to provide grassroots innovators of plant based knowledge an incentive to disclose knowledge.*⁷⁰

The overall policy of the Government of India towards traditional medicine includes programmes for applying methodologies of modern science to traditional medicine as well as scientifically validating the systems and presenting them in the scientific idiom.⁷¹ This would naturally lead to the application of IPR regimes to TM also resulting in much rigour, particularly in the drug formulation stage.

Although India does not have a national policy on TK, the National Intellectual Property Rights Policy 2016 (National IPR Policy) contains specific recommendations on TK. In fact, by including TK protection within the ambit of the IPR Policy, India has raised the level of protection that it would like the holders of such knowledge to that of the owners of other IPRs. The Vision statement of the Policy itself talks about the role of IP to promote, *inter alia*, traditional knowledge and biodiversity resources. The Policy also mentions the necessity to create awareness of TK, GR and TCE & Folklore. (p.8). Holders of TK, TCE & folklore are one of the target groups for the same (p.9). It also acknowledges that there is considerable unexplored potential for developing, promoting and utilizing TK which it considers a unique endowment of India. It is gratifying to note that the policy advocates that activities for the promotion of TK have to be conducted with the effective participation of TK holders (p.11). It made a very specific action point that India's rich TK should be promoted with effective involvement and participation of TK holders who should be provided with necessary support and incentives for furthering the "knowledge systems that they have nurtured from the dawn of our civilization" (p.14).

Regarding the Traditional Knowledge Digital Library (TKDL), the policy has recommended expanding its ambit and using it in future for R&D. It also recommended documenting oral TK with adequate precautions to maintain its integrity and with safeguards to prevent misappropriation (p.13). Apart from the recommendations on the general TK, the Policy takes note of TM. It makes the detailed observation that "India is rich in traditional medicinal knowledge which exists in diverse forms in our country. Amongst them, well-developed systems like Ayurveda, Yoga & Naturopathy, Unani, Siddha, Sowa-Rigpa and Homeopathy have immense economic value. It is important to protect such knowledge, be it oral or in codified form, from misappropriation, while providing space and environment for dynamic development of traditional knowledge for the benefit of mankind." (p.15). This succinctly

puts India's overall approach to TK as for the benefit of all humanity but that it should be protected from misappropriation. Hence the Policy recommends that India should engage actively and constructively at various international fora to develop legally binding international instruments to protect TK, GR and TCE, obliquely referring to the three draft legal texts before the WIPO IGC. While speaking about the benefits of IP reaching holders of TK, the Policy also is aware of issues that the AYUSH industry is facing about BDA and recommends formalization of a consultation mechanism for harmonious implementation of the BDA. Overall, the National IPR Policy has made a good number of recommendations for protecting TK though it has not recommended separate legislation for the same. The Policy should serve as the guiding principles for policy and lawmakers.

The extension of modern IPR regimes to ITM poses many problems because of the peculiarities of the systems and IP laws. For instance, patent law requires a specific act of innovation for the grant of a patent and still not recognises 'collective' or 'community' rights. Most innovations in ITMs are adaptations of existing formulae, which may be incremental and informal innovations. They are many a time result of open-source research rather than closed-circuit research within the walls of one or a limited number of laboratories and, possibly, with bit-by-bit additions by several persons. The social dimension needs to be an intrinsic part of any IPR policy regarding the ITM because of the way the R&D is done in those systems. IPRs, particularly patents, will have to accommodate the principle of collective rights. There is already a precedent to this in the case of GIs. As per the GI Act, a single individual cannot even apply for registration of a geographical indication. Only an association of persons or producers or an organisation or authority established by law can apply for registration of a GI.⁷² The rights on a geographical indication accrue to all registered authorised users, on the number of which there is no restriction.⁷³ This model can be explored in the case of the extension of a *sui generis* protection system for the IP inherent

in traditional medicine systems. Though patents cannot be fixed to a geographical area, a community collectively applying for a patent may be possible, but it will require accepting a community group as an ‘entity’ like a company incorporated.

Protection of IPRs in ITMs Abroad

The issue of IP protection for ITM became a priority concern when instances came up of such knowledge getting patented in other countries. One of the most celebrated cases is that of the turmeric patent referred to previously. Another case was the European Patent Office patent number 436, 257 of 1994 granted to the W R Grace Company and the US Department of Agriculture for a method for controlling fungi on plants with the aid of hydrophobic extracted Neem (*Azadirachta indica*) oil. A group of Indian non-governmental organisations filed an opposition to this patent in 1995 and submitted documentary proof to the effect that the fungicidal properties of Neem were known in India for a long time. Based on the evidence submitted by the patent challengers, the EPO revoked the patent in 2000.⁷⁴

Even where the pharmaceutical companies or individuals have done the research and found valuable properties in formulations and ingredients described in ancient texts of the ISMs, which entitled them to genuine patents, they have benefitted greatly from the knowledge through savings in the cost of screening. The discovery of a new drug entails tests and trials with thousands of molecules and many years of research involving millions of dollars in expense.⁷⁵ In the case of components used in traditional medicine formulations, the chances of success are much higher than average, and the field of initial probing is very limited. In these cases, in the absence of any IP protection, the research companies do not have to pay any royalty or, licence fee to the knowledge holder.

The patenting of certain properties of turmeric and neem and other such cases prompted the government to examine defensive measures that could be adopted to prevent the wrong patenting of Indian traditional

medicinal knowledge. The principal reason for such existing knowledge getting patented in the developed countries was the absence of a database on such knowledge with the patent offices concerned for conducting prior art searches. No patent can be granted on an invention which has been published anywhere in the world and is already in use, as per the norms of the Paris Convention and the TRIPS Agreement. Patent Examiners find out this through a search of certain databases and other documents available with the Patent Offices. Unfortunately, Indian traditional medicine knowledge was not available in such searchable databases. Therefore, the government decided to create such a database which resulted in the Traditional Knowledge Digital Library (TKDL).

The TKDL (Traditional Knowledge Digital Library) contains information on traditional knowledge, particularly knowledge relating to traditional medicine in India in a digital database comparable to a patent database. What the TKDL project did was translate the formulations and other prescriptions in the authoritative texts of Ayurveda, Siddha, Unani and Yoga into modern languages. These were then converted into the format of the specifications in a patent application and digitised in an easily searchable format. The database is in five languages, namely, English, French, German, Spanish and Japanese. For this purpose, a Traditional Knowledge Resource Classification (TKRC) containing several thousand sub-groups was prepared modelled on WIPO's IPC. These are related to medicinal plants, minerals, animal resources, effects and diseases, methods of preparations, mode of administration and so on. As of 2 December 2022, more than 424,000 traditional medicine formulations and processes have been included in the database. The system-wise breakup is given in Table 4.⁷⁶

Table 4: TKDL: Texts used for Transcription

Discipline	No. of texts (including volumes) used for transcription
Ayurveda	119
Unani	91
Siddha	55
Yoga	15
SowaRigpa	01
Total	281

Source: Author's compilation based on data on TKDL website at tkdl.res.in.

The database is offered free to patent offices but under a non-disclosure agreement. The non-disclosure commitment is to guarantee against the misuse of traditional medicinal knowledge. The Patent offices of Australia, Canada, Chile, Denmark, Europe, France, Germany, India, Japan, Malaysia, Peru, Russia, Spain, the United Kingdom, and the USA have already concluded such agreements and are accessing the TKDL. Based on the TKDL, many patent applications have been rejected and many withdrawn.⁷⁷ As per the terms and conditions of the Access agreement, examiners of the patent office can utilize TKDL for search and examination purposes only and cannot reveal the contents of TKDL to any third party unless it is necessary for citation. TKDL Access Agreement is unique and has in-built safeguards on non-disclosure to protect India's interest against any possible misuse. As per information available on the TKDL website, there have been 58 cases of withdrawal of patent applications in the European Patent Office, 19 applications declared 'dead' in the Canadian Intellectual Property Office, one application terminated in the UK Patent Office and one application withdrawn in the US Patent and Trademark Office because of prior art evidence in the TKDL. Claim amendments have been made in 29 cases in various patent offices. Further, because of the existence of the TKDL, the number of applications for patents on the traditional medical knowledge of India has been decreasing in the USPTO and EPO over the years.

The TKDL is primarily a knowledge database of ITM, as could be seen in Table 4. It is essentially a defensive mechanism to prevent persons from taking patents on existing formulations and processes as well as the properties of ingredients described in the ITM texts. Since July 2009, it has been able to affect 272 patent applications, of which almost half are in the European Patent Office. The Patent Office-wise break up is presented in Table 5⁷⁸.

Table 5: TKDL Impact on Patent Applications (2009-2022)

Sl. No.	Patent Office	No. of Cases
1	European Patent Office (EPO)	135
2	Indian Patent Office (Office of CGPDTM)	61
3	Canadian Intellectual Property Office (CIPO)	36
4	US Patent & Trademark Office (USPTO)	29
5	IP Australia (AIPO)	10
6	UK Patent & Trademark Office (UKPTO)	01
	Total	272

Source: Author's compilation based on data on TKDL website.

Most of the applications were withdrawn or rejected and few amended the claims. However, it is a matter of concern that even after so many years, the number of patent offices with access to the TKDL is limited.⁷⁹ This is a matter that requires policy intervention from the government. It is heartening to note that in August 2022, the Cabinet has approved widening access of TKDL database to users, besides patent offices.

Protecting Traditional Medicine: An assessment of Current Status

Generally, the discussions at the international level on traditional medicine tended towards safeguarding the same from misappropriation and patenting by outsiders. This came from the perception that TMK is not based on laboratory-generated innovations that required big investments,

and, therefore, IPR protection as an incentive to invest in R&D for innovations in the sector is not required. Therefore, the legal protection available under various international treaties was towards regulating the access and exploitation by outsiders of traditional knowledge. Wherever access is to be granted the same has to be based on prior informed consent and access and benefit sharing agreement. International law considered this as a safeguard mechanism for the practitioners of the knowledge to get fair returns from the exploitation of the knowledge. A consequence of this is that if an invention based on TMK sought patent protection, it has to establish that access to the knowledge has been obtained under the above-mentioned route. While countries like India have provided for this procedure, countries like the USA have not provided for the system of PIC and ABS mechanism. In such countries patenting of TMK can happen with no benefit sharing with the holders.

Grant of patents to TMK, under the existing laws, will be subject to the patentability criteria laid down in the TRIPS Agreement. This will exclude all knowledge which is already in the public from getting patented.

At the same time, there are many hurdles for TM-based innovation patents. The very same provisions incorporated in the Act as TK protection measures create a bulwark which is rather difficult to overcome. Clauses (e), (i) and (f) of Section 3 are considered by many as standing in the way of TM innovations getting patents. At the same time, it may be noted that Section 3 (e) and (i) are general provisions and do not refer to TK or TM which do not debar TM innovation patents, unlike the case with Section 3 (p).

TM Related Patent Applications in India

A search of the patent database of India has brought out that there were 2599 applications during the period from 13 October 1999 to 10 September 2022 in which the abstract contained the term ‘herbal’

showing a connection with plants. The system-wise search showed the results presented in Table 6.

Table 6: TM-related Patent Applications in India⁸⁰

Keyword	Title		Abstract		Complete specification	
	Published	Granted	Published	Granted	Published	Granted
Ayurveda	09	00	104	08	1398	255
Yoga	23	02	52	01	508	48
Unani	15	13	42	12	373	80
Siddha	17	00	30	02	287	54
Homoeopathy	07	01	13	02	243	40
Tibetan	00	00	05	02	78	20
Marma	00	00	03	00	12	01
Phytochemicals	44	06	146	13	1390	207

Source: Author's compilation.

In these applications, the fields of invention mostly are chemical, biotechnology, biochemical and so on. The subject fields into which Indian Patent Examiners are divided are the following: Biochemistry, Biotechnology, Biomedical Engineering, Chemistry, Civil Engineering, Computer & IT Engineering, Electrical, Electronics and Communication Engineering, Food Technology, Medical Engineering, Metallurgical Engineering, Physics, Polymer and Textiles. However, the major fields of technology in which patent applications get filed are the following: Chemical, Pharmaceuticals, Polymer Science & Technology, Computer/Electronics, Communication, Electrical, Physics, Biomedical, Mechanical, Biotechnology, Biochemistry, Food, Microbiology, Metallurgy and Material Science, Textile, Civil Engineering, General Engineering, Agrochemicals, Agricultural Engineering and Traditional Knowledge. Of these, the year-wise number of applications received under TK from 2015-16 to 2019-20 are as presented in Table 7.

Table 7: Number of Patent Applications under TK (2015-2020)

Year	Number
2015-16	114
2016-17	84
2017-18	87
2018-19	74
2019-20	11

Source: CGPDTM Annual Report 2019-20. pg.38.

As per this data, the number of applications in the TK category has been steadily declining over the years.

A company-wide search yielded the following results. Dabur Research Foundation has applied for 94 patents of which 42 were granted, but most of which are related to non-Ayush fields. Hamdard has applied for 47 of which it received patents for 17. Patanjali has 43 published applications but no granted patent. Himalaya Wellness has 21 applications in its name but no patent. Baidyanath has 3 published applications of which 2 were granted and one is under process. However, one of the granted ones is awaiting NBA clearance before notifying. Zandu Ayurveda has one granted patent. Company-wise search is not definitive since the search items will include not only pharmaceuticals but also other areas of technology and within pharmaceuticals, it does not make a distinction between Ayush systems and modern medicine. The pharmaceutical firms Glaxo, Marico, Hindustan Unilever and Lupin Laboratories, who are also leading Ayush firms⁸¹ have 300, 16, 2792 and 82 Indian patents respectively, but mostly in non-Ayush fields. A simple keyword search with ‘plants’ in the complete specification of granted patents has yielded a return of 24,389 documents⁸².

To draw a definitive picture of patenting of TM in India, one will have to scrutinise almost all patents. At least a scrutiny of the 1543 herbal-related patent documents (as per complete specification) or at least 438 granted patents in which the title itself contains the word ‘herbal’,

will have to be made⁸³. Many of them may be TM-related patents. For example, the complete specification of the granted patent 366860 (on 17.05.2021) for “Herbal Compositions for Management of Liver Disorders and Method Thereof” Specifically states that ‘Herbal medicine has been used for centuries in rural areas by local healers, several substances used in modern medicine for the treatment of many diseases have originated from research on medicinal plants’. The main claim is for “a hepato-protective herbal composition, comprising of (a) a pharmaceutically effective amount of extract of *Alternanthera sessilis*; and a pharmaceutically effective amount of extract of *Piper nigrum*.” The documents used in FER include, ‘Traditional Phyto-therapy with herbal compositions used by folk practitioners of Tripura (North East) for treatment of various diseases (2014), and “Exploring Traditional Medicine: Report of a Symposium.”

An indicative list of probable Ayurveda, Yoga, Unani and Siddha-related patents, based on complete specifications, is given in Annexures 1-4.

There are concerns voiced in informal discussions with the industry that the Patent Office is very strict in the applications that have TK connections. So far as India is concerned, Section 3(p) specifically excludes patents for TK. The Patent Office Guidelines lay the following guiding principles for examining TK-related patent applications.⁸⁴

If the subject matter as claimed relates to extracts/alkaloids and/or isolation of active ingredients of plants, which are naturally/inherently present in plants, such claims cannot be considered novel and/or inventive when the use of such plants is pre-known as part of teachings of Traditional Knowledge. For example, an extract of the *Withania* plant for the management of stress.

A combination of plants with known-therapeutic effects with further plants with the same known-therapeutic agents wherein all plants are previously known for treating the same disease is considered

to be an obvious combination. For example, a composition comprising of *Calendula officinallis*, Aloe vera and *Centellae asiatica* as a healing agent and for the treatment of wound

In case an ingredient is already known for the treatment of a disease, then it creates a presumption of obviousness that a combination product comprising this known active ingredient would be effective for the treatment of the same disease. An example is a combination of five constituents, one of these being a 1:2 watery extract of *Cucumis melo* containing catalase and superoxide dismutase; along with *Pimienta racemosa*, *Citrus aurantifolia*, Coenzyme Q-10 and *Pyridoxine chlorhydrate* for the treatment of vitiligo.

Discovering the Optimum or Workable Ranges of Traditionally known ingredients by Routine experimentation is not inventive. Eg. a formulation comprising at least two of the following: an extract of *Pongamia pinnata* (in the range of 2 to 20 percent), an extract of *Lawsonia alba* (in the range of 5 to 15 percent), an extract of *Dhatura alba* (in the range of 2 to 20 percent) and an extract of *Cocos nucifera* (in the range of 20 to 60 percent) for the management of chronic ulcer, diabetes ulcer, and the management of bleeding in cuts and wounds

In case multiple ingredients are known to have the same therapeutic activity as per traditional knowledge, taking one single component out of them cannot be considered inventive. E.g., an extract of *Zingiber zerumbet* (bitter ginger) for inflammation and for an allergic disorder like Asthma

In case individual ingredients are already known for the treatment of a disease as a part of Traditional Knowledge, then it is obvious that a combination product comprising these known ingredients with further plants with the same known therapeutic effect would be more effective than each of the medicinal plants when applied separately (additive effect).e.g. a composition comprising of theanine (Tea) and a herb selected

from *Sankhapuspi*, *Satavari* or a mixture thereof for the treatment of a disease (cold and/or influenza) related to reduced immunity.

The critics of the Guidelines mention the following:

- It is unnecessary to indicate the source of the material used for exhibiting the efficacy in some cases where patents are applied for innovative processes or steps applied in a process, whereas the Guidelines do not make this distinction.
- When prior art does not mention the particular extract or alkaloid, the method of extraction and its use ought to be considered.
- It is incorrect to presume the additive effect of a combination of drugs, even when we know the individual properties of each of the ingredients since the synergic effect could be different from the combination of individual effects. (*Each herb in a poly-herbal formulation may have a synergistic effect; bio-enhancer property; adverse effect lowering attribute; capacity to activate a pro-drug (inactive molecule); ability to facilitate excretion of its metabolites; and many more such specific roles hence, a formulation with multiple herbs should not be misunderstood as a mere combination of herbs.*)⁸⁵
- Patents may be granted for “unique” combinations, like those involving the selection of specific ingredients, in specific proportions, processed under specified conditions. The addition of perfume/ flavour, stabilizers or penetration enhancers or standardization of the product or novel delivery systems can all contribute to uniqueness (Patwardhan: 2013).

It has been argued that better extraction techniques, better dosage forms or stable formulations, processes for improving the bioavailability of the drug or for establishing synergistic/antagonistic activities and biotechnological interventions with an aim of standardization, fractionation, or isolation of active ingredients of the drug should be made patentable (Patwardhan:2013).

Demands have been voiced at different fora for amending or clarifying certain provisions in the Patents Act.

- Section 3(e) of the Patents Act which states that a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance is not patentable should be modified to state that “processing of a natural product or mixture of natural materials (minerals, metals, flora, fauna and products derived from them) doesn’t debar the invention from a ‘process patent’ if it advances the industrial applicability/safety/effectiveness of the product”.⁸⁶
- Section 3 (j) that excludes from patentability of “plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals” may include an explanation to the effect that “technique for cultivation/ propagation of endangered medicinal plants of critical value in Ayush systems doesn’t debar the invention from a ‘process patent’.”⁸⁷
- In Section 3(p) which rules out patents for traditional knowledge, an explanation to the effect that the ‘proprietary’ formulations in Ayush systems do not debar the invention from a ‘product patent’ if it is tenable from a regulatory perspective and is proved to be safe and effective as per the requirements of the extant regulatory provisions.⁸⁸

Indian Patent Law and TM Patents: Case Studies

Three randomly selected sample cases are presented below to understand some of the issues concerning patent applications in the field of TM in India. One case relates to an application which was withdrawn by the applicant later, another one relates to an application rejected by the Patent Office and a third one pertains to a granted application. All applications were published in the Patent Journal and examined, as per the Patent Rules.

Case Study 1: Application No. 3854/DEL/2011

This is an application for the grant of a patent for a novel herbal extract of *Jasminum humile* and its therapeutic uses as an anti-diabetic and anti-oxidant submitted on 28 December 2011. The applicants were Parminder Nain, Vipin Saini, Sunil Sharma, and Jaspreet Nain. It was put under the category ‘Traditional Knowledge Biotechnology’. It was published on 5 July 2013 and a request for examination was filed on 27 December 2015. There were 8 claims, the principal one being that “a composition derived from the leaves of *Jasminum humile* for therapeutically (*sic*) uses in antidiabetic and antioxidant comprising aqueous extract of *Jasminum humile*, glibenclamide and vehicle”.

The First Examination Report (FER) was issued on 19 February 2019. The FER observed that the invention has industrial applicability but lacks inventive steps and falls under the non-patentability clauses Section 3(d), (e), (i), and (p). It cited a US patent application No. US200300737291 and Indian publications to disprove the inventiveness claims. As regards non-patentability, the FER observed that in the absence of experimental data, it is not clear if the said composition act to provide an enhancement of the known efficacy i.e., demonstrate a greater technical effect and/or differ significantly in properties w.r.t the known compounds. It also observed that the formulation is a mere admixture of known ingredients. It is also not clear if the combined agents act together to provide a technical effect that is greater than just the sum of the two or more agents alone, or whether the combination is a mere juxtaposition with no interaction of the agents. The percentage/ratio of ingredients should be provided with a synergistic effect and the synergistic effect should be shown with the help of supporting examples. The claims also fall under section 3(p) of the Patents Act, 1970 as the medicinal property of all the extracts and the minerals given the composition claim are known in traditional knowledge and section 3 (i) as the same is for the treatment of diabetes when administered in dosage form, which is directed towards the method of treatment of human being.

In a reply dated 19 August 2019 the applicant claimed that the study preceding the application provide *in vivo* evidence that leaves extract of *Jasminum humile* possess significant antidiabetic activity in streptozotocin-induced type-2 diabetes mellitus in rats.

The Patent Office held the view that:

- Both the constituents of the claimed composition are known in the prior art. Hence objected u/s 2(1)(ja). It also held that the subject matter of claims 1-8 are not patentable u/s 3 (d) of the Act as it claims for two components for therapeutic use as anti-diabetic and antioxidant, but both the claimed components are individually known in the prior art for the same therapeutic purpose, hence it is obvious for the person skilled in the art to use both the known components for the known purpose. Thus, the claimed composition is objected u/s 3(d).
- The subject matter of claims 1-8 are not patentable u/s 3 (e) of the Act as it claims for two components for therapeutic use as anti-diabetic and antioxidant but no ratio/percentage of either individual component or relative ratio/percentages of both the components is given, hence when in the prior art both the components are individually known for the same therapeutic purpose the, enhanced technical effect is expected by a combination of both the components. Hence, there is no synergism between the claimed components as composition. By merely stating ‘composition’ does not make a composition unless and until there is a synergism between the two components to show an enhanced therapeutic effect when compared to the individual components. Hence, claims 1-8 are not allowable u/s 3(e) of the act for lack of synergism.
- The subject matter of claims 1-8 are not patentable u/s 3 (p) of the Act as it claims for *jasmine humile* which is known in TKDL.

A hearing was scheduled for 5 July 2022. However, the application was withdrawn on 4 July 2022.

The following observations can be made on the case:

- The drafting of the application left much to be desired. For example, the title itself was rather confusing: “A Nobel extract of *Jasminum humile* and its therapeutically (*sic*) uses in Antidiabetic and antioxidant”.
- It failed to mention the particular prior art documents (patent and non-patent literature)
- It failed to establish the novelty of the invention as claimed
- The first claim lacked clarity.
- The drafting should have been done keeping in mind the various clauses of Section 3 of the Patents Act.
- The replies to the FER were merely repetitive.

Case Study No. 2: Application No /1294/CHENP/2010

This is an application for the grant of a patent for “Anti-Adipogenic Compositions Containing Piper Betel and Dolichos Bifloras” made by Gokaraju Ganga Raju. It was under the category of agrochemicals. The invention related to herbal compositions for inhibition, amelioration, or prevention of adipogenesis-mediated diseases such as obesity, lipid storage disease and hyperlipemia, comprising a biologically effective amount of extract or fractions from *Piper betel* in combination with one or more extracts or fractions derived from *Dolichos bifloras*, *Commiphora mukul*, *Boerhaavia diffusa*, *Tribulus terrestris* and *Zingiber officinale*, as active ingredients and optionally containing a bio-enhancing agent or a bio-protecting agent along with biologically acceptable carriers or diluents. The invention further relates to a method for treating or preventing adipogenesis-involved diseases in mammals using the invented compositions. There were 22 claims the principal claim being for Anti-adipogenic herbal compositions for inhibiting or preventing or amelioration of disease conditions associated with adipogenesis in mammals comprising an effective amount of extracts or purified fractions derived from *Piper betle* and/or *Dolichos bifloras* along with biologically

acceptable excipients. The application itself referred to several US and other patents as well non-patent literature as prior art.

On the publication of the application, the TKDL raised on 4th June 2012 a pre-grant objection stating that in TKDL there are several references where *Piper betle*, *Dolichus biflorus*, and *Piper nigrum* have been used alone and along with few other ingredients as an anti-obesity agent and for the treatment of obesity through oral administration in the Indian systems of medicine and hence there is no novelty or inventive step in the applied invention. In reply, the applicant on 11 January 2016 submitted that the TKDL references disclose crude formulations and do not talk about anti-adipogenic compositions as claimed in the application.

Patent Office made the following observations also, in addition to the TKDL objections, in the FER on 7 September 2020 and scheduled a hearing on 12 October 2020.

- The subject matter of claims 1-19 is anticipated given all following documents and thus lacks inventive step u/s 2(1) (ja) of Patents Act 1970:
 - US Patent No. 6413553 discloses a herbal formulation comprising Piper betel extracts formulated with pharmaceutically acceptable carriers and the Piper betel leaf is extracted with water. And further additives that are combined with the Piper betel extract can be starch-gelatin paste and a binder. The composition may be administered orally and the ratio of Piper betel extract to the other extract in the composition is 1:1 to 1:5, which anticipates the range claimed in the instant application. The formulation comprising Piper betel extract is administered in a dosage form to a patient and is used to treat humans.
 - Muthu et al Indian J Pharmacology April 2006; Vol 38, Issue 2, 131-2. discloses administering a methanol extract of *Dolichos biflorus*, wherein the part of the *Dolichos biflorus* extracted is the whole plant (which reads on leaves, since the whole plant

contains leaves) in an amount of 200 mg/kg or 400 mg/kg, given to rabbits in combination with food (which reads on dietary forms), wherein the methanol extract of *Dolichos biflorus* has antioxidant activity. The extract does not require any additional ingredients.

- Arambewela *et al.* International Journal of Food Science and Technology 2006, 41 (Supplement1), pages 10-14 disclose an ethanol extract of *Piper betle* leaves has antioxidant activity. Arambewella further teaches that the ethanol extract of *Piper betle* leaves can be added to food, including aloe gel(which reads on dietary forms and also reads on gel), and can be combined in an amount of 0.2 mg/mol r 0-50 micrograms/ml which reads on the amounts claimed in the instant application, since the amounts can be adjusted to provide the amounts in the percentage claimed). The extract does not require any additional ingredients.
- Therefore, because of the above disclosures, it would be obvious to a person skilled in the art to arrive at the composition of the present invention. Therefore inventive steps cannot be acknowledged for claims 1-19 under section 2(1)(ja) of the Patents Act, 1970.
- The present application falls within the scope of Section 3(p) of the Patents Act of 1970. In TKDL about 49 references are given for the treatment of obesity using *Piper betle* and *Dolichus biflorus* composition. There are other documents also which refer to a formulation containing *Dolichus biflorus* for the treatment of obesity. The claimed composition from *Piper* and *Dolichus* for the treatment of obesity is known traditionally from the Indian system of medicines which is also disclosed in the specification.
- The subject matter of claims falls under section 3 of the Patents Act, 1970 and is not allowable under the said section/clause:
- a) Claims 1-19 fall within the scope of section 3 (d). The extract compositions as defined in the claims are not novel and inventive and

would be considered as “same extract compositions or combination of known extracts” as in the prior art.

- b) Claims 1-19 fall within the scope of section 3; no composition or dosage has been disclosed.
- c) Claims 13-15 fall within the scope of such clause (n) of section 3 of the Patents Act- presentation of information claims are not patentable.
- Claims 13-15 do not constitute an invention u/s 2(1)(j) of the Indian Patents Act, since neither process nor product has been defined.
- The applicant fails to provide the NBA permission document in accordance with the Patents Act.

The Controller after hearing the applicant concluded that:

- This invention is a mixture of already existing TKDL biological materials and their new use which has no technical advancement and surprising effect over the cited prior art documents by the opponent. Biological materials Piper betle Linn, Dolichos biflorus Linn, Piper nigrum Linn taken in the present invention have already been used as herbal compositions in different ways. The present invention does not fulfil the Guiding Principle 3,6: In case an ingredient is already known for the treatment of a disease, then it creates a presumption of obviousness that a combination product comprising this known active ingredient would be effective for the treatment of the same disease.
- The claims do not constitute an invention u/s 2(1)(j) and are non-patentable under section 3(p) of the Patent Act.

Therefore, the grant of the patent was refused under Section 25 (1) on 11.3.2021.

The following observations are made on the case:

- The invention is based on TK and TK assertions are generally very wide and many a time encompass a large field of cures. It is practically difficult to identify a patent claim that is outside of it.

- It needs to be proved beyond reasonable doubt that there is a novelty that goes beyond prior art and involves an inventive step which does not occur to a person ordinarily skilled in the art.
- Claims should be drafted keeping in mind that the presentation of information is not patentable.
- The patent examination and adjudication process are very time-consuming. In this case, it has taken 11 years; 14 years if we take the PCT international filing date which is 24.9.2007.

Case Study 3: Application No. 202011007071

This is an application for the grant of a patent for a Polyherbal Unani Formulation Majoon Suranjan Effective Against Cancer Cells alone as well as in combination with the anticancer drug Sorafenib by Deepthi Singh. The field of the invention is Chemical. The IPC classifications are: A61K0031440000, G01N0033680000, C07D0213810000, G01N0033500000, C02F0009000000

The application stated that Majoon suranjan is a polyherbal Unani formulation used in the treatment of rheumatoid arthritis (RA). It has anti-inflammatory activity. Sorafenib is a type of targeted cancer drug called a cancer growth blocker. This invention is directed towards studying the effect of Majoon suranjan in combination with Sorafenib in decreasing the per cent cell viability of both the cancer cell lines. The application stated that Majoon suranjan along with sorafenib showed a greater decrease in cell viability as compared to when sorafenib was given alone. The data suggest that Majoon suranjan along with sorafenib inhibits the growth of cancer cells and could be used as a potential adjuvant in cancer patients undergoing sorafenib-based therapy. The applicant made 4 claims, including for processes, the principal one being a novel herbal composition of Majoon suranjan in an amount of (100, 250 and 500 µg/ml) and Sorafenib in an amount of (1, 2 and 5 µM) effective against cancer cell lines (Dul45 and Huh 7). It was published on 10 March 2020.

The FER observed that the prior art document discloses sorafenib as an anticancer drug and other documents disclose Majoon Suranjan as an anti-arthritic formulation. Therefore, the use of both the combination for cancer cell line growth inhibition is obvious to a person skilled in the art and an inventive step for the subject matter of claims 1-4 cannot be acknowledged as per requirement u/s 2(1)(ja) of the Patents Act.

In response, it was submitted by the applicant on 23 September 2021 that Majoon suranjan was not known in cancer treatment before, that none of the prior arts shows any combination like the claimed combination, that none of the prior art either in isolation or in combination teaches or motivates a person having ordinary skills to arrive at the present invention.

The patent was granted on 23 August 2022 for

- A novel herbal composition of Majoon suranjan in an amount of (100, 250 and 500 μ g/ml) and Sorafenib in an amount of (1, 2 and 5 μ M) along with the DMSO as a pharmaceutical excipient.
- The composition of claim 1, wherein the composition is in the form of a pill, tablet, capsule, liquid, powder, or suppository.
- A process for the preparation of a novel herbal composition effective against cancer comprising the steps of mixing the ingredients in the amount specified in claim 1 at room temperature while stirring continuously to make the mixture homogenous.

The lessons one can draw from this case are:

- Claims should be drafted precisely
- Replies to FER should be specific and to the point
- Novelty and inventive steps must be stated in scientific terms.

Some of the problems that Ayush patent applicants face, as coming out of the random scrutiny of some of the granted and rejected applications are the following:

- Poor drafting of the application
- Failure to establish novelty with reference to prior art
- Failure to establish inventive steps through precise scientific methodology
- Generalised claims
- Non-fulfilment of requirements like production of NBA clearance for notification of the granted patents
- Failure to establish the synergic effect.

Why Positive Protection: Arguments for

An important question is whether patents are important for Traditional Medicine. Conceptually, New Chemical Entities (NCEs) are not part of TM. Plants and other natural products are used in TM to make various formulations based on the set principles in classical texts or folk knowledge. The research in the field is not aimed at discovering or developing new Active Pharmaceutical Ingredients (APIs) which can form the base of formulations, unlike the case with modern medicine. Traditionally, the practitioners used to make medicines from crude drugs or prescribe the ingredients and method of preparations to the patients. Separate manufacturing companies are a new phenomenon in Traditional Medicine in India developed in less than 150 years. Dabur India, established in 1884, set up the first manufacturing plant to mass produce Ayurvedic formulations in 1896. Other companies followed: Himalaya Drug Company in 1930, Charak pharma in 1947 and Vicco Laboratories in 1952. The others are of more recent origin, though Amrutanjan Healthcare, which produces and distributes allopathic and ayurvedic products has been in existence since 1893.

The setting up of the above and other Ayush pharma production units is a transformation from a service-dominated sector to a pharmaceutical sector (Harilal: 2008), a kind of hesitant industrialisation. Earlier it was home productions only. Now separate manufacturing units made their appearance gingerly. The emergence of an Ayush pharma industry in

place of the earlier home productions could be one reason for the current interest in patenting. Industry requires capital investment and capital gains in monopoly, which is provided by patents. It is, therefore, natural that as an industry, Ayush pharma argues for IPR protection.

Many arguments can be advanced for granting patent protection to TMK. But the first question to be answered is what objectives are to be achieved by IP protection for Traditional Medicine. Correa has summarised the possible objectives as under:

- Saving data (Conservation)
- Collecting data
- Preventing erosion of knowledge
- Ensuring continuous improvement/innovation
- Contributing to self-determination
- Benefit sharing
- Economic development/commercial exploitation.

After examining the other tools available, he has concluded that IPRs may be relevant to promote the commercialisation of TM but not very relevant or completely irrelevant to the other possible objectives. Collection and compilation of the knowledge can be done through administrative efforts as in the case of the Traditional Knowledge Digital Library (TKDL) and People's Biodiversity Register (PBR).⁸⁹ The issue of self-determination is rather extraneous to the question. Benefit sharing is already provided under CBD and BDA. One can argue that innovation and commercial exploitation of the innovations as the main objectives of the IPRs. These, in any way, are the main arguments for IP protection for all technologies and not only for TM. The current international and national IP regimes have been framed with these objectives.

Arguments have been advanced that patenting of TM medicines be promoted to share advantages of the global economy which will open up a potential avenue for developing countries to benefit from the

knowledge economy and that modified forms of TM be considered for patenting (Chaudhary A & Anr. 2012). It has also been suggested that the nutritional and cosmeceutical products of Ayurveda have the potential for getting patents. Marketing the products globally can indeed lead to an economy of scale in manufacturing.

At the same time, one can raise certain ethical and philosophical arguments for extending IP protection to TM. These include, *inter alia*, considerations of equity and justice. It is natural justice that the creators and preservers of knowledge in a traditional way ought to be recognised and compensated for the use of the same by others, as in the case of new inventions in the modern ways of knowledge creation. Inventions and innovations in all fields need to be encouraged and incentivised and TM cannot be an exemption from that. Unlike the case with modern medicine, most of the TM has never enjoyed IPR protection and, therefore, deserves to be protected.

Another argument in favour of positive IP protection for TM is that it may bring better economic returns and social recognition to TM practitioners. After the TRIPS Agreement (1994), the IP system has an overarching role in the economy and society. A common notion is that new products and processes need to be patented for validation. In the absence of that, they do not get due recognition. In economic terms, a patent is a valuable asset. A patent undoubtedly raises the academic profile of the innovator (s) and encourages respect for the knowledge, both within the community and outside (Correa. 2001).

One possible reason for the secrecy associated with TMK is the fear of losing the possible economic returns from the same. A patent guarantees that for the period of the patent, that is, 20 years, all rights remain with the patentee and that person can derive economic returns from the same. This would also imply that many of the secret TMK holders will be more willing to disclose the knowledge if they are assured of economic returns through the IPR system.

Some of the arguments advanced for IP protection are summarised in the following quotation from a report of the Crucible Group (2001)⁹⁰:

Vesting legally recognized ownership of knowledge in communities through sui generis IPRs will raise the profile of that knowledge and encourage respect for it both inside and outside the knowledge-holding communities. This will make the learning and development of such knowledge a more attractive prospect for the younger members of such communities, thus perpetuating its existence. The possibility of economic returns for the use of that knowledge by third parties acts as a further incentive for community members to respect their knowledge and continue to engage in practices in which that knowledge is used and generated. Indigenous and local knowledge holders will be more willing to disclose otherwise secret knowledge once they know sui generis laws can give them control over how their knowledge gets used. In this way, IP laws encourage the disclosure, use and proliferation of the knowledge that might otherwise be lost.

It is also to be noted that TMK is not static but dynamic. Innovations and improvements do happen there. In place of earlier decoctions, pastes, *choornas* and a limited number of pills, now tablets and formulations with long shelf life are getting manufactured. This is a result of innovations. It is necessary to encourage innovations.

Traditional Medicine and innovation are not antithetical. The knowledge itself has evolved as a result of several innovations, though in a traditional way, possibly over a long period. The WHO Global Strategy and plan of action on public health, innovation and intellectual property (2008) makes a specific recommendation that policies on innovation in the field of TM be promoted (para 3.4, page 31) and encourage research on mechanisms for action and pharmacokinetics of TM. (p.32). The overall approach of the Strategy is also to prevent the misappropriation of TK which is possible if it is available in a digitally searchable database.

The most important argument for patent protection for TM is that a patent grants exclusive rights to the product or process to the patentee. These rights will include the right to manufacture, sell and import. This will mean that only the patent owner or with a licence from the owner can use, manufacture, or sell or import that product or use the process.

An appropriate patent system in a proper economic milieu may attract investment in R&D and incentivise innovation in the sector.⁹¹ It is possible that a monopoly right can attract more investment, particularly in innovation in the sector as it gives investors a greater opportunity to recoup their investments. More innovation is likely to result in more products and processes, which may have better therapeutic effects and commercial attractions.

Issues and Challenges to IPR protection for TM

The nature of TMK poses challenges for IP protection. A patent is granted to a new product or process only, whereas TMK relates to a product or a process which is in existence. An economic argument for the grant of patents is that it is necessary to incentivise innovation which requires huge investment, particularly pharmaceutical ones. The patents are granted at a national level and for a maximum of 20 years only subject to annual maintenance by paying a fee in each of the countries where the patent is granted. In the case of medicines, there can be compulsory licences for public health emergencies, subject to certain provisions. The general criteria of patentability as laid down in the Paris Convention and the TRIPS Agreement are not subject or discipline-specific. Article 27 of the TRIPS Agreement says that “patents shall be available for any inventions, whether products or processes, in all fields of technology” and that the patent rights are enjoyable without discrimination as to the field of technology. The challenges these poses are the following:

- Traditional Medicine cannot be treated as a separate category for the grant of patent rights
- There cannot be any special treatment or exception that applies to traditional medicine only to the exclusion of other technological

fields, unless the terms are couched in such a broader way, as India did with the drafting of Section 3(d) of the Patents Act, 1970.

- The period of protection has to be the same as the one provided to other technological fields.

The term ‘traditional medicine’ itself is a big disincentive to innovation and IPR. In international discussions, Western medicine got the nomenclature ‘modern medicine’ and became the mainstream system in every country. WHO’s health strategy and advisories are modern medicine based. Discussions on health are in the language of Allopathy. TM stands as opposed to scientific medicine. The validation of medicines is to be as per scientific principles, which means what is accepted in modern medicine. Different phases of clinical trials, blind random trials, are the way to find out the effectiveness and tolerance including adverse effects of a medicine. Diagnosis is to be as determined by various tests done by technicians and not by the treating physician.

The historical use of formulations by the TM systems without adverse effects is not considered scientifically acceptable evidence. As per the Concise Oxford Dictionary (Ninth Edition), the word ‘traditional’ means, “based on, or obtained by tradition” and tradition means “a custom, opinion, or belief handed down to posterity especially orally or by practice”. While in Ayurveda there are families who have been practising the same for generations, the younger ones learning from their elders, the fact that the same can be learnt in a formal setup and that there are textbooks on the subject have been largely ignored in this nomenclature. Even now it is a reluctant acceptance that there can be innovations in TM, but the innovations are considered minor improvements or adaptations of the existing knowledge. The systems also place many hindrances to innovation. Some practitioners hold to the divine origin of Ayurveda, and almost all consider the basic principles laid down in the classical texts as unalterable. A different, scientific approach that allows questioning the principles also is required to make the systems really scientific. Discussions on the protection of TM suffer from two infirmities, namely

(i) an imperfect understanding of the systems, and (ii) associating TK with biodiversity.

Issues of misappropriation of TM evoked moral indignation from many who felt that it is not fair, and principles of equity and justice demanded that the people who conserved and protected the knowledge for a long time ought to be rewarded. That is how the PIC and ABS regimes came into existence. Those regimes per se were not for encouraging innovations and IPRs within the TM systems, but for ensuring ABS for commercialisation of innovations in all fields. The political clubbing of the adjective 'indigenous' to the traditional medicine holders further limited it to the medicinal knowledge of 'indigenous' communities.

The issue of the patentability of TM raises many other questions. Biological resources form the base of most TM. They may be used alone or in combination and either in raw form or in a slightly modified form such as dried, powdered, boiled and so on. It has been a long-accepted doctrine in patent law that a product of nature is not eligible for a patent.⁹² The TRIPS Agreement also excludes from patentability all living organisms with the exceptions of micro-organisms and new plant varieties (Article 27). The issue of the patentability of materials existing in nature that have just been isolated or purified or slightly altered remains controversial (Correa: 2001). Many countries like the USA and those in the European Union favour granting patents to biological material including isolated cells and genes, though products of nature doctrine still holds. Since TM products are not separated cells or genes, they find it difficult to get patents.

An argument that is often raised against the eligibility of TM for patents is that it does not have individual inventors; it is the community. TM does not preclude individual innovation and individual knowledge. In fact, it has both community knowledge and individual knowledge. "Possession of knowledge by individuals, in effect, does not mean that such knowledge is perceived by communities as not belonging to them" (Correa 2001). Grant of patents means a grant of private rights in place

of the existing community rights, a concept well enshrined in the CBD and BDA. While patent laws recognise corporate rights, the concept of community rights has not made inroads into that.

However, it may be possible to claim protection on extracts or formulations of natural products. Correa presents examples of US patents on hypoallergenic stabilized aloe vera gel (No. 4178372), Aloe vera ointment (No. 4725438), and material extracted from coco leaves (No. 4696819) and EPO patent No 05113671 on *Commiphora wightii* (guggule or mukul myrrh). (Correa 2001). Novel production and extraction processes are generally eligible for patents. For example, the process patent for Jeevani in India.

There is also the issue of capacity of the knowledge holder to present the case in a language that is understood by patent examiners. For example, the disclosure of the invention should be in a manner sufficiently clear and complete for the person skilled in the art to carry it out, but since the patent examiners are persons from modern science, this is not an easy task. Another challenge is the reluctance of the knowledge holder to reveal the same, as is the case with folk medicine practitioners.

Risks in Patenting TM

A concept integral to IPRs is that of the ‘public domain’. The simple explanation of the concept is that works and products outside IPR protection are considered to be in the public domain, that is, the public can freely use the same without any specific authorisation from the IPR holder. As of now, the concept of ‘public domain’ has no relevance for TMK. Being part of the modern IP system, it does not take into account domains established by customary and indigenous laws (Taubman: 2007; Gibson: 2007; Tulalip Tribes: 2003). Patent grants in TM can lead to the argument that what is not patented is in the public domain and should be freely usable by everybody. This would create a conflict situation with existing laws like Biological Diversity Act in India. Further, it will dent the arguments for Section 3(p) of the Patents Act, i.e. “an invention

which in effect is traditional knowledge or which is an aggregation or duplication of known properties of a traditionally known component or component” cannot be patented. It is likely to lead to the misappropriation of knowledge. Grant of patents cannot be restricted by subject or country. The law cannot lay down that TM practitioners, whether traditional or registered or traditional medicine firms, only can apply for a patent. If patents are to be granted, they will be open to all, including modern pharmaceutical firms. When a medicinal product is considered a new medicine (novel), logically that will have to satisfy all the requirements of modern medicine to be brought into use. That includes the requirement of having randomised clinical trials to ensure the safety and effectiveness of the medicine for getting marketing approvals.

The concepts of ‘non-discrimination’ and ‘national treatment’ enshrined in the TRIPS Agreement would open patenting of TM to all, including big corporations. Is such a situation advisable is a matter to be considered in-depth. If Ayurveda or other ISMs are to be treated on par with modern medicine in every respect for purposes of patenting, then this will have to be done.

Another risk is that as of now, TMK is protected against misappropriation for an indefinite period in countries like India through legislations like the BDA and the Patents Act though developed countries do not extend any such protection. But once they are opened to the patent system, the rules of the patent will apply, and the patented knowledge will fall under the public domain after the expiry of the patent period.

Conclusion

One suggestion made by some pro-patent advocates is to grant utility model patent to TM. Around 73 countries and regional patent offices⁹³ have this system in operation though not for TM. Utility models are also known as “short-term patents”, “innovation patents” and “utility innovations”. The procedure and criteria for the grant of Utility Models are generally less strict than that for the grant of patents. Many a time it

is considered at a local level only and is generally used by locals only though legally there is no bar on foreign applicants. Some countries do not insist upon a prior substantive examination of the application unless there is an objection before registration⁹⁴ (WIPO). According to WIPO, “utility models are considered particularly suited for protecting inventions that make small improvements to, and adaptations of, existing products or that have a short commercial life”.⁹⁵ Utility models are not referred to in the TRIPS Agreement and, therefore, dereliction of TRIPS obligations does not arise in case a country passes a law for the same. In many countries it is granted to mechanical inventions only; technical, chemical, and biological processes are not eligible, though there are variations among the countries. In the Indian context, however, the grant of utility model protection to chemical or biological processes is likely to dilute section 3(d) of the Patents Act, which was introduced to ward off the evergreening of patents by pharmaceutical companies. Therefore, it is not an advisable option for TM products. Further, Section 3(d) has not been such an unsurmountable bulwark to getting patents. During the short period of 4 years since the amendment of the Act, from 2005 to 2008, there were 67 patents for new forms of a known substance and 19 patents for combinations, all in the modern pharmaceutical industry (James. 2009). Relaxing S.3(d) would contribute to the trend of evergreening by modern pharma.

There are also suggestions that instead of or in addition to the existing IPR system, a *sui generis* system of protection is devised for TM. That is a new system that accommodates the special characteristics of TMK. As Correa points out, “due to the principle of territoriality, protection at home would neither prevent the misappropriation of the protected knowledge in other countries nor allow the TK holders to obtain any type of protection abroad” (Correa:2002). He in his 2002 paper raises the following questions concerning the proposal for a *sui generis* law:

- Who the titleholders are and how are they represented.
- What is the subject matter of protection.

- What are the eligibility requirements and modes of acquisition, possibly including registration.
- What kind of rights are to be granted (exclusive rights, or merely remuneration or moral rights).
- What should be the duration of protection and its possible retroactive application.
- What are the sanctions to be prescribed for infringement; and
- What are appropriate enforcement mechanisms.

The *sui generis* law will have to accommodate the different kinds of TM in existence the world over and also give due regard to the protection systems existing under the customary laws. It also will have to overcome the biggest hurdle, which is international acceptance, which is as of now an insurmountable one, considering the experience of the discussions in the WIPO IGC.

Yet another suggestion is that the Trade Secret system be used for the protection of TK, including TM. It also has been observed by the protagonists of this view that institutions to safeguard the trade secrets of indigenous and local peoples are either weak or absent in most countries (Mugabe:2001). In the case of ISMs like Ayurveda, this may not be an option as the knowledge is already disclosed in recorded texts. Trade secrets, though, may be a means to protect tribal and folk medicines. However, India does not have any separate law on Trade Secrets.

IPR regimes emerged as an incentive for the commercialization of research results and literary and artistic works. The exclusive rights guaranteed by the IP laws ensure that when new products and processes are brought into the market, others will not copy the same. In the absence of such a system, the inventors and investors will be reluctant to share the new knowledge publicly. One of the arguments for patenting TM is that it will incentivize investment in the sector. The monopoly or exclusive rights guaranteed by patents may indeed encourage investment in the TM pharma industry. At the same time, the question to be answered is

whether the absence of patenting has in any way stood as a disincentive for investment.

The growth of TM pharmaceutical companies does not give credence to the thinking that the absence of IPR has stood in the way of investment. So far as Indian systems of medicine are concerned, IPR systems play a peripheral role only in commercialisation since the systems market mostly time-tested formulations and processes. However, as a medical system to tackle new diseases and health challenges as impressed by the COVID-19 pandemic, the need for further R&D for new formulations and processes cannot be ruled out. To face the new challenges of health care, the systems have to gear up and encourage innovations. Because of the unique nature of these systems, the innovations they introduce may not meet the strict criteria of novelty and inventiveness required for patents. India has provided registration as *Patented and Proprietary Drugs* for new formulations⁹⁶ in ISMs, under the Drugs and Cosmetics Act but that alone may not be adequate to encourage innovative efforts in the sector. Ways and means will have to be explored to extend IP-like protection but with norms that fit into the ethos of these systems.

In the case of ITMs, it may be necessary to have certain special treatments in the IPR regime given the characteristics of these systems. The systems are well structured and well developed over millennia and based on certain sound norms. Innovations in ISMs are necessarily to be different from those in modern medicine. In the ISMs, traditional research and innovation as well as R&D in the modern sense are being taken up. As the head of one of the leading Ayurvedic firms stated in an interview, the development of new formulations takes 10-12 years of R&D including clinical trials.⁹⁷ Such investment in time and resources needs to be protected to encourage further research and development. Extension of IP protection is one of the tools for that. The policy of the Government of India has been towards encouraging the ISMs to undertake R&D and providing them IPR protection. The existing laws protect the

ISMs from misappropriation and also provide means for securing rights on innovations. They and other laws also contain provisions to safeguard the availability of quality raw materials. At the same time, the industry needs guidance on availing of the provisions.

The way forward must be decided by due consideration to (a) basic principles of systems like Ayurveda, and (b) risks of patenting as brought out above. It may involve a reversal of many policies that have been followed by India, both domestically and globally, for the past many decades. Therefore, any policy decisions will have to carefully weigh the benefits and risks. A detailed study on ‘patenting and commercialisation of ITMs’ can throw light on the economic need and benefits of patenting in ITMs. This study should also explore the patenting and commercialisation of ITM in the USA and Europe. It should identify all patents granted in the field in all major patent offices. While this may take time, immediate steps can be taken to encourage innovations and facilitate patenting of such innovations in TM. One mechanism which can be considered is the setting up of a Patent Facilitation Cell with medical and IP law experts under the Ministry of Ayush. Some of the functions that the Cell can perform are listed below:

- Conduct programmes on innovation in TM
- Organise IP awareness programmes for TM practitioners, researchers and firms
- Help in drafting patent applications
- Provide free patent search facilities to innovators
- Provide free non-binding informal preliminary examination reports (not a substitute for Patent Office FERs.) to the potential patent seekers to help them to take informed decisions about the course to be taken.

The Cell can also commission a complete search of patent databases to find out the actual status of patenting of TM in India and draw lessons from the same for future innovators.

Endnotes

- ¹ Capitalism is “an economic system, dominant in Western world since the breakup of feudalism, in which most means of production are privately owned and production is guided and income distributed largely through the operation of markets”. (Robert L. Heilbroner in the Encyclopedia Britannica online edition, accessed on 30 September 2022). Feudalism is described as a “historiographic construct designating the social, economic, and political conditions in western Europe during the early Middle Ages, the long stretch of time between the 5th and 12th centuries”. (Elizabeth A.R. Brown in the Encyclopedia Britannica. Online edition. Accessed on 30 September 2022).
- ² There is no general agreement on the beginnings of capitalism. However, Encyclopaedia Britannica states that the continuous development of capitalism as a system dates only from the 16th century and was spearheaded by the growth of the English cloth industry during the 16th, 17th, and 18th centuries. (<https://www.britannica.com/topic/capitalism>). But it emerged as a proper system only in the 18th century and in 1848, Marx and Engels predicted its spread as a worldwide system.
- ³ Available at https://avalon.law.yale.edu/18th_century/anne_1710.asp.
- ⁴ The Congress shall have power “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.” US Constitution Article 1 Section 8 Clause 8.
- ⁵ Convention establishing WIPO was signed at Stockholm on 14 July 1967, and it became specialised agency of the UNO in 1974. See wipo.int.
- ⁶ TRIPS Agreement (1994). Part II.
- ⁷ Article 3 of the TRIPS Agreement
- ⁸ Article 64 *ibid*.
- ⁹ Article 4^{bis} of the Paris Convention.
- ¹⁰ Till the TRIPS Agreement, the period of patent protection was 14 years only.
- ¹¹ Article 31 of the TRIPS Agreement.
- ¹² The original signatories of the Paris Convention (1883) were Belgium, Brazil, France, Guatemala, Italy, the Netherlands, Portugal, El Salvador, Serbia, Spain and Switzerland, and of the Berne Convention (1886) were Belgium, France, Germany, Haiti, Italy, Liberia, Spain, Switzerland, Tunisia and the United Kingdom.
- ¹³ Title 35 US Code Section 102 stated until 2011 that a person is not entitled to a patent if the invention was “known or used by others in this country, or was patented or described in a printed publication in this or a foreign country” before the date of invention by the applicant for the patent. Prior knowledge or use in a

different country is not a bar to a patent application in the US. However, a prior patent or a printed publication anywhere in the world will be a bar to a patent in the US. This was changed by the America Invents Act, 2011, effective from September 2012.

- 14 WIPO. Glossary of Key Terms Related to Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions. Document code WIPO/GRTKF/IC/44/INF/7.
- 15 WIPO/GR TKF/IC/40/4 dated 9th April 2019.
- 16 WHO Traditional Medicine Strategy 2002-2005, p. 7.
- 17 Jayaraman, K. US patent office withdraws patent on Indian herb. *Nature* **389**, 6 (1997). <https://doi.org/10.1038/37838>. Also <https://patents.google.com/patent/US5401504A/en>
- 18 Ibid.
- 19 Indigenous Community Bans TNC Researchers by Someshwar Singh in Third World Network, Geneva dated 24 February 2020. Available at <https://www.twn.my/title/bans.htm>. Accessed on 7 September 2022.
- 20 Legal Elements of the “Ayahuasca” Patent Case AUTHOR: Center for International Environmental Law (CIEL), Washington DC, USA DATE: 30 March 1999 SOURCE: various environmental law listservers URL: <http://www.econet.apc.org/ciel/> and <https://www.ciel.org/project-update/protecting-traditional-knowledge-ayahuasca/>.
- 21 CIEL was acting on behalf of on behalf of the Coordinating Body of Indigenous Organizations of the Amazon Basin (COICA in Spanish) and the Coalition for Amazonian Peoples and Their Environment (Amazon Alliance).
- 22 CIEL. Protecting Traditional Knowledge: Ayahuasca Patent Dispute. In Campaign Update. Available at <https://www.ciel.org/project-update/protecting-traditional-knowledge-ayahuasca/>. Accessed on 15 September 2022.
- 23 <https://patents.google.com/patent/US6673377B1/en>.
- 24 <https://patents.google.com/patent/US7556830B2/en>.
- 25 WORLD TRADE Organization. Ministerial Conference. Second Session, Geneva 18 and 20 May 1998. Statement Circulated by Mr. Ramakrishna Hegde, Minister of Commerce. WT/MIN(98)/ST/36 dated 18 May 1998. Page 5. Available at https://www.wto.org/english/thewto_e/minist_e/min98_e/mc98_e/engstate_e.htm.
- 26 Ghazala Javed, Priya Ritu, Deepa V K. 2020. Protection of Traditional Health Knowledge: International Negotiations, National Priorities and Knowledge Commons. Sage Journals. 9olume: 6 issue: 1, page(s):98-120. <https://doi.org/10.1177/2393861719883069..>

- ²⁷ <https://en.unesco.org/>
- ²⁸ The Patents Amendments Act 2005. Section 30 (3A) and (3B). https://www.wipo.int/tk/en/databases/tklaws/articles/article_0021.html
- ²⁹ See wipolex.wipo.int/en/text/585084.
- ³⁰ This and the following 2 sections are based on an earlier study by the author published in 2017 (James:2017)
- ³¹ Section 3 (p) of the Patents Act, 1970.
- ³² Section 25 (1) ((k) and (2) (k) *ibid*.
- ³³ Section 64 (1) (q) *ibid*.
- ³⁴ Section 2(1) (j)
- ³⁵ Chaturvedi, Sachin (2007) Kani Case. A Report for GenBenefit, available at: www.uclan.ac.uk/genbenefit
- ³⁶ Indian Patent No. 236637
- ³⁷ Indian Patent No. 210329
- ³⁸ Indian Patent No. 208437
- ³⁹ Indian Patent No. 184109
- ⁴⁰ Indian Patent No. 218675
- ⁴¹ Indian Patent No. 244034
- ⁴² Indian Patent No. 233430
- ⁴³ Indian Patent No. 237192
- ⁴⁴ Indian Patent No. 203986
- ⁴⁵ Indian Patent No. 221770
- ⁴⁶ Press Information Bureau release dated 13 August 2013.
- ⁴⁷ <http://164.100.47.194/Loksabha/Questions/QRresult15.aspx?qref=39760&lsno=17>.
- ⁴⁸ <https://ipindiaservices.gov.in/PublicSearch/>.
- ⁴⁹ This is an incorrect depiction of PIC codes.
- ⁵⁰ End note 45 *supra*.
- ⁵¹ Section 2(1) (e) of the Geographical Indications of Goods (Registration and Protection) Act, 1999.
- ⁵² <https://ipindia.gov.in/registered-gls.htm>.
- ⁵³ Section 15 (2) of the PPV and FR Act, 2001
- ⁵⁴ Section 39 (1) (iii) *ibid*
- ⁵⁵ Section 30 (a) *ibid*.
- ⁵⁶ Section 29 (1) *ibid*.

- ⁵⁷ Preamble to the Biological Diversity Act, 2002.
- ⁵⁸ Sec 3 (1) *ibid* covers access to “biological resources occurring in India or knowledge associated thereto for research or for commercial utilization or for bio-survey and bio-utilization”.
- ⁵⁹ Section 3 (1) *ibid*.
- ⁶⁰ Section 6 *ibid*.
- ⁶¹ Item 9 (iii) of Form 1.
- ⁶² Section 3 (1) of the Act
- ⁶³ Section 2 (i) *ibid*.
- ⁶⁴ Sections 33C and 33D of the D&C Act.
- ⁶⁵ Section 3 (a) and (h) and First Schedule of the Act. Section 3 (h) *ibid*. It reads, “‘patent or proprietary medicine’ means, in relation to Ayurvedic, Siddha or Unani Tibb systems of medicine all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurveda, Siddha or Unani Tibb systems of medicine...” The Act keeps this as separate from ‘Ayurvedic, Siddha or Unani drug which includes “all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in the authoritative books of Ayurvedic, Siddha and Unani Tibb systems of medicine.”
- ⁶⁶ The registrations are done at state level.
- ⁶⁷ Allahabad High Court. Cattle Remedies And Anr. vs Licensing Authority/Director Of ... on 18 January, 2007. Indian Kanoon - <http://indiankanoon.org/doc/1811328>.
- ⁶⁸ It was approved by the Cabinet on 4th October 2002.
- ⁶⁹ National Policy on Indian Systems of medicine and Homoeopathy – 2002, Para 8.1 available at http://www.whoindia.org/LinkFiles/AYUSH_NPolicy-ISM&H-Homeopathy.pdf.
- ⁷⁰ *Ibid*, para 16.4.
- ⁷¹ AYUSH in India – 2007, p.1.
- ⁷² The Geographical Indications of Goods (Registration and Protection Act, 1999, section 11(1).
- ⁷³ Section 17 *ibid*.
- ⁷⁴ *Ibid*, p.114-116.
- ⁷⁵ “It takes about 10-15 years to develop one new medicine from the time it is discovered to when it is available for treating patients. The average cost to research and develop each successful drug is estimated to be \$800 million to \$1 billion. This number includes the cost of the thousands of failures: For every 5,000- 10,000 compounds that enter the research and development (R&D) pipeline, ultimately only

- one receives approval” [Pharmaceutical Research and Manufacturers of America Brochure on Drug Discovery And Development,(2007) available at http://www.phrma.org/sites/default/files/159/rd_brochure_022307.pdf
- 76 Source: <http://www.tkdل.res.in/tkdل/langdefault/common/Home.asp?GL=Eng> accessed on 12 September 2022.
- 77 See <http://www.tkdل.res.in/tkdل/langdefault/common/Abouttkdل.asp?GL=Eng>
- 78 <http://www.tkdل.res.in/tkdل/langdefault/common/outcomemain.asp?GL=Eng> Accessed on 12 December 2022.
- 79 Fifteen only as of 02 December 2022.
- 80 <https://ipindiaservices.gov.in/publicsearch>. Searched on 30 September 2022.
- 81 Ayush Sector in India: Prospects and Challenges. RIS. 2021. Page 4.
- 82 ipindiaservices.gov.in/PublicSearch/PublicationSearch/Search. Dt. 30.9.2022
- 83 ‘Herbal’ in complete specification
- 84 Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material (2012)
- 85 Ayush Ministry Presentation to a group on 17 September 2022.
- 86 Ibid.
- 87 Ibid.
- 88 Ibid.
- 89 Rule 22(6) of the Biological Diversity Rules 2004.
- 90 As quoted in Correa (2001).
- 91 33 US 127 (1948).
- 92 The countries include: Albania, Antigua and Barbuda, Argentina, Armenia, Australia, Austria, Belarus, Belize, Botswana, Brazil, Bulgaria, Chile, China, Costa Rica, Croatia, Czech Republic, Denmark, Dominica, Dominican Republic, Egypt, El Salvador, Estonia, Ethiopia, Finland, France, Georgia, Germany, Ghana, Greece, Guatemala, Honduras, Hungary, Indonesia, Ireland, Italy, Japan, Kazakhstan, Kenya, Kyrgyzstan, Lao People’s Democratic Republic, Malaysia, Mexico, Mongolia, Mozambique, Oman, Namibia, Nicaragua, Panama, Paraguay, Peru, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Serbia, Slovakia, Slovenia, Spain, Swaziland, Tanzania, Thailand, Tonga, Trinidad and Tobago, Turkey, Uganda, Ukraine, United Arab Emirates, Uruguay, Uzbekistan, Viet Nam, ARIPO, OAPI and Andean Community.
- 94 WIPO website. https://www.wipo.int/patents/en/topics/utility_models.html
- 95 Ibid.
- 96 See note 30 supra

⁹⁷ Ravi Prasad, Executive Chairman, Himalaya Drug Company in an interview in the Times of India, New Delhi, dated 14 January 2012.

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Annexures

Annexure 1: Granted Indian Patents with “Ayurveda” in the complete specifications Total 266

Sl. No.	Application Number	Title
1	202141023369	Automated Ayurvedic device for Kayasheka-Pizzicchil therapeutic procedure
2	202011056345	Formulation of Anti-Epileptic Herbal Composition Comprising Extracts of Martynia Annuu and Albizia Lebbeck
3	202021053836	“A Foot Crack Healing Formulation and the Method Thereof”
4	202021053356	Lipstick With A Push And Pop Mechanism.
5	202011047280	Cow Urine with Reduced Ammonia and Urea
6	202021038777	Shirodhara Apparatus
7	202021034516	“A Process for Preparing Immediate Release topical Formulation of Pterocarpus Marsupium Roxb”
8	202021034438	"Cement Based Ecofriendly Material Mix and Non-Load Bearing Type Products Therefrfom"
9	202021018894	A Herbal Shaving Gel Composition
10	201941054463	Glycyrrhiza Glabra Gel as An Intra Canal Medicament in Endodontic Treatment of Permanent Teeth
11	201941047908	Dental Varnish Composition, Methods of Preparation and Use Thereof
12	201941026097	Automatic Cleaning System for Sink in Therapeutic Emesis
13	201941026095	Advanced Automated System or Instrument for Therapeutic Emesis
14	201911018961	A Herbal Anthelmintic Formulation And Process Of Its Preparation
15	201941010339	Process Of Extraction Of Anticancer Activity Exhibiting Novel Compound 4,8-Dihydroxybenzo [De]Chromen-2(4h)-One From C.Coriaria
16	201911007661	Broad Spectrum Sun Protective Topical Formulation
17	201921001871	Metal Composite Container for Storing Liquid

18	201821050059	Herbal Formula Containing Gymnosporia Montana Leaf Extract for The Treatment of Liver Diseases
19	201821045878	Herbal Oral Contraceptive Formulation
20	201821014019	A Multi-Functional Panchakarma Table
21	201824036719	A Self-Cleaning Ion-Eluting Unit and Process Thereof
22	201837026112	A Cosmetic Composition and The Use Thereof for Regulating Skin Quality
23	201821004235	Nicotine – Free Smoking Compositions as Well as Nicotine Containing Smoking Compositions Based on Panchagavya with The Combination Of Herbal Leaves
24	201741036569	System And Method for Creating an Environment for Rejuvenating the Degenerated Organs of a Human
25	201721035434	Application Of Bermuda Grass (Cynodon Dacylon) For Phytoremediation of River Water.
26	201741033167	A Synergistic and Non-Toxic Combination for Treating Liver Disorders
27	201741032340	Irrigating Solution Composition with Extracts of Cocos Nucifrea
28	201741032339	Gel Formulation of Cocos Nucifera Husk Extract
29	201741030554	"Process For the Preparation Herbal Drinking Water"
30	201741002385	Hair Growth Retardant Composition
31	201731001972	Hybrid Cotton Patch and a Method for Its Fabrication
32	201731001942	Herbal Preparation for Therapeutic and Prophylactic Management of Neurological Disorders
33	201721000834	Process Of Preparing Herbal Composition for The Treatment of Osteoporosis
34	201631034147	A Process for Preparing an Anti-Hypertensive Herbal Composition
35	201611031283	A Novel Synergistic Herbal Composition
36	201611030748	Highly Potent Synergistic Composition of Jatyadi Oil and Achyranthes Aspera (Apamarga) Extract for Therapeutic Applications
37	201611024962	A Single Step Process for The Production of Ethylp-Methoxycinnamate from Kaempferia Galanga Linn.
38	201611023226	Herbal Composition for Therapeutic Management of Respiratory Tract Diseases
39	201611007752	Herbal Formulation for Treating Disease and Complications Caused by The Malarial Parasite

40	201641001693	A Process for The Production of Alkyl Coumarate Concentrate from Ipomoea Carnea Subsp. Fistulosa
41	6738/CHE/2015	Tri-Molecular Complex Of Natural Compounds
42	1180/KOL/2015	Poly Herbal Formulation
43	6152/CHE/2015	Anticancer Potential Of 11-Hydroxy 12-Methoxy Dihydro Kawain From Piper Betle L. Leaves
44	5076/CHE/2015	"A Formulation For Diabetic Foot Ulcer And A Process For Preparation Of The Same"
45	2429/ MUM/2015	System And Method For Pain Remedy And Rehabilitation
46	630/KOL/2015	Curcumin Infused Milk Beverage And A Process For The Preparation Thereof
47	1885/ MUM/2015	A Method For Producing Boerhavia Diffusa Callus
48	1407/ MUM/2015	Synergistic Skin Lightening Composition For Inhibiting Synthesis Of Melanin
49	3687/DEL/2014	Herbal Composition For Thrombocytopenia
50	1698/DEL/2014	A Synergistic Pharmaceutical Composition For Gastrointestinal Disorders
51	860/DEL/2014	Anti Diabetics Agents, Compositions And Process For Preparing The Same
52	931/MUM/2014	A Topical Antimicrobial Herbal Formulation
53	838/MUM/2014	Development Of Antimicrobial Silver Nanoparticle Dispersed Gel For Wound Healing
54	999/CHE/2014	Herbal Composition For The Treatment Of Enteritis And Process For Making The Same
55	227/KOL/2014	A Pharmaceutical Composition From Wheat Grass For Treatment Of Iron Overloaded Diseases And A Method Thereof.
56	35/KOL/2014	Herbal Composition For Prevention And Treatment Of Respiratory Distress In Birds And Feed Thereof.
57	2824/DEL/2013	A Process Of Transformation In Withania Somnifera Plants To Increase Secondary Metabolite Content
58	2145/DEL/2013	Proteaseomal Inhibitors Useful For Osteogenic Activity And Pharmaceutical Composition Thereof [Osteo-Heal]

59	2625/CHE/2013	Novel And Synergistic Composition Of Lecithin And Lysolecithin For Improving Bioavailability And Solubility Of Hydrophobic Compounds And Extracts
60	1720/MUM/2013	A Herbal Based Medicinal Composition
61	1530/MUM/2013	Method For Preparation Of A Herbal Contraceptive Composition
62	1547/CHE/2013	Antiarthritic Composition Containing Mucilage Of <i>Cardiospermum Halicacabum</i> For Increased Bioavailability Of Antiarthritic Drug Used For Treating Rhumetoid Arthritis
63	278/DEL/2013	A Process For Preparation Of Ayurvedic Formulations
64	1835/MUM/2012	Herbal Composition For Alleviation Of Pain In Joints
65	5294/CHE/2012	Herbal Formulation For The Treatment Of Arthritis
66	3680/DEL/2012	A Novel Sugar Free Asava Formulation And Process Of Preparation Thereof
67	3371/MUM/2012	"Ksharsutra Carrier Cum Application Device"
68	2832/MUM/2012	Formulation For Improved Bioavailability Of Resveratrol And Process For Preparation Thereof
69	4824/CHE/2012	Pharmaceutical Compositions Comprising <i>Costus Igneus</i> Extract
70	1284/KOL/2012	Herbal Composition And Medicament For Treating Malaria.
71	1177/KOL/2012	"An Oral Herbal Extract Composition For Use In Treating Cerebral Malaria"
72	3040/MUM/2012	Herbal Composition And Medicament For Treating Malaria
73	2965/DEL/2012	A Novel Synergistic Herbal Formulation Of <i>Withania Somnifera</i> For Antihyperlipidemic And Antiobesity Activity
74	3662/CHE/2012	Skin Lightening Agent And Skin Lightening Compositions Comprising The Same
75	2578/DEL/2012	Future Magic Bullet Of "Polyherboceutical Formulation" For Treatment Of Hypertension.
76	2504/DEL/2012	Method For Isolation Of Pyrrolizidine And 2-Methyl Pyrrolidine From <i>Ocimum Sanctum</i> And Its Use Thereof

77	2199/ MUM/2012	A Process For Preparation Of Herbal Gelatine
78	734/KOL/2012	Herbal Composition And Medicament Thereof For Treating Epilepsy
79	1841/ MUM/2012	Flavonoid (Baicalein) Production In Cell Cultures Of <i>Oroxylum Indicum</i> (L.) Vent.
80	1660/ MUM/2012	A Computer Implemented System And Method For Facilitating Selection Of Bedding Products
81	1650/DEL/2012	"Novel Compounds As Memory Enhancers"
82	2019/CHE/2012	Novel Highly Bioavailable, Water Soluble, Sustained Release Nanoformulations Of Hydrophobic Plant Derived Compounds, And Extracts
83	1192/DEL/2012	"A Novel Composition For Herbal Hand-Wash And Process For The Preparation Of The Same"
84	936/MUM/2012	A PROCESS For PREPARATION Of Gelled ENEMA COMPOSITION
85	601/MUM/2012	"Pellets Of Herbal Extracts And Process For Preparing The Same"
86	3425/ MUM/2011	Process For Triterpene With Anti-Cancer And Analgesic Activity From <i>Euphorbia Neriifolia</i> .
87	3369/ MUM/2011	"A Medicinal Formulation For Use In Protection From Gamma Irradiation"
88	3034/ MUM/2011	Continuous Pelletisation Plant
89	2277/CHE/2011	A Novel Polyherbal Formulation With Multiple Therapeutic Effects As Antidiabetic, Antifatigue, Hepatoprotective And Antioxidant
90	2165/DEL/2011	A Formulation For The Treatment Of Arsenic Toxicity
91	482/KOL/2011	A Novel Synergistic Herbal Composition For Use In Treating Head And Body Aches
92	486/KOL/2011	A Synergistic Herbal Extract Composition Effective Against Gastro-Intestinal Endoparasitic Infections In Animals
93	431/KOL/2011	Herbal Compositions And Medicaments Thereof For Treatment Of Muscular Pain
94	1113/ MUM/2011	A Herbal Medication To Cure Jaundice
95	780/DEL/2011	Anti Diabetic Composition Of Fractions Of The Fresh Cow Urine And Process For The Same

96	444/MUM/2011	"A Novel Herbal Composition For The Treatment Of Wound Healing"
97	3538/MUM/2010	Curcumin Monosulphate, Its Salts, Process For Synthesis Thereof And Treatment Of Cancer
98	1738/MUM/2010	Compositions For Inhibiting The Growth Of Mammalian Hair
99	3259/MUM/2010	"A Process For The Preparation Of Ethanolic Extract From Alternanthera Bettzichiana"
100	3256/MUM/2010	"Biotransformation Of Biologically Active Compounds From Medicinal Plants"
101	2939/MUM/2010	Herbal Composition And Ingestable Capsule Containing The Same For Accelerated Healing And Reunion Of Fractured Bones
102	2770/MUM/2010	Disinfectant And Method For Its Preparation And Use
103	1070/KOL/2010	Electrolyte Fortifying Composition For Recharge, A Hydrating Snack, And Process For Preparing The Same
104	1071/KOL/2010	Calcium Fortifying Composition For Strength, A Hydration Supplement, And Process For Preparing The Same
105	1072/KOL/2010	Zinc And Copper Fortifying Composition, A Hydrating Supplement, And Process For Preparing The Same
106	1068/KOL/2010	Chromium And Boron Fortifying Composition, A Hydration Supplement, And Process For Preparing The Same
107	2735/CHE/2010	Process For Preparation Of A Hexane Extract Of Aegle Marmelos Fruit
108	2306/MUM/2010	Sodium Free Food Preservative
109	1942/DEL/2010	"Scar Primers And A Kit For The Authentication Of Unani Drug Senna (Cassia Acutifolia & Cassia Angustifolia) From Its Adulterant (Cassia Tora & Cassia Sophera)".
120	1943/DEL/2010	"Scar Primers And A Kit For The Authentication Of Unani Drug Mulethi (Glycerrhiza Glabra) And Its Adulterant Abrus Precatorious".

121	1944/DEL/2010	"Scar Primers And A Kit For The Authentication Of Unani Drug Filfil Siyah (Piper Nigrum) And Its Adulterant Carica Papaya".
122	1945/DEL/2010	"Scar Primers And A Kit For The Authentication Of Unani Drug Zarishk (Berberis Aristata) And Its Adulterant Daru Haridra (Coscium Fenestratum)".
123	1947/DEL/2010	"Scar Primers And A Kit For The Authentication Of Unani Drug Zaafran (Crocus Sativus) And Its Adulterant Qurtum (Carthamus Tinctorious)".
124	1948/DEL/2010	"Scar Primers And A Kit For The Authentication Of Unani Drug (Rewand Chini) Rheum Emodi And Its Adulterant Rheum Palmatum".
125	1946/DEL/2010	"SCAR Primers For The Authentication Of Unani Drug Zizyphus Jujuba And Its Adulterant Jhad Beri (Zizyphus Nummularia)"
126	2356/CHE/2010	A Pharmaceutical Composition Of Reformulated Turmeric Extract And A Method Thereof
127	1890/DEL/2010	"Scar Primers And A Kit For The Authentication Of Unani Drug Amla (Emblica Officinalis) And Its Adulterant Shakarkand (Ipomeae Batatas)"
128	2317/CHE/2010	An Automation System For Recipe Management In A Defined Environment
129	1671/CHE/2010	Low Sodium Compositions For Condiments For Food, Methods Therefor And The Condiments So Obtained
130	1001/DEL/2010	"A Process For The Preparation Of Amla Chips"
131	719/MUM/2010	A System For Determination Of Pulse Strength
132	114/DEL/2010	A Novel Process Of Dyeing And Processing A Natural Textile Product Using Natural Dyes Alongside Neem And Tulsi
133	3095/CHE/2009	A Process For Preparing A High Fibre Nutritional Food Product And The Food Product Obtained Thereby
134	2713/MUM/2009	Topical Medicinal Formulation
135	2465/MUM/2009	Herbal Calf Starter Compositions
136	2329/MUM/2009	Herbal Milk Replacer Compositions For Calf

137	2272/DEL/2009	"A Process For Preparation Of Herbal Aphrodisiac Hard Boiled Candy Formulation"
138	1736/DEL/2009	"Scar And A Kit For The Authentication Of Single Drug Tukhm-E-Kasoos (Cuscuta Reflexa) And Its Adultcrant Aftimoon Vilayati (Cuscuta Chinensis)"
139	1634/DEL/2009	"A Method For Preparation Of Andrographolide From Andrographis Paniculata"
140	764/MUM/2009	Topical Pharmaceutical Formulation
141	465/DEL/2009	"System And Method For Brand-Promotion Through Phone/Mobile Technologies"
142	284/DEL/2009	"A Process For Preparation Of Gingerol Enriched Ginger Conserve"
143	166/DEL/2009	"A Herbal Hair Oil- A Novel Hair Nourishing Anti Dandruff Herbal Oil
144	2451/DEL/2008	A Homeopathic Preparation For Treatment Of Animals Suffering From Intestinal Parasites Worms Infection And Associated Constipation, Stomach Bloating Etc
145	1882/DEL/2008	"A Method Of Preparing New Anti Cancer Herbal Medicine And Product There Of"
146	1381/DEL/2008	"Jaisalmeri Preserve And Candy From Fruit Of Toosh (Citrullus Colocynthis)."
147	940/MUM/2008	Homeopathic Combination Treatment To Heal Neurological Disorders
148	851/ MUMNP/2008	Herbal Composition For Inflammatory Disorders
149	2079/ MUM/2007	Herbal Composition For Reducing Add/Adhd And Method Thereof
150	876/DEL/2008	"Herbal Composition For Chin And Neck Firming"
151	679/DEL/2008	"Herbal Composition For Hips,Thighs And Arms Firming"
152	661/DEL/2008	"Herbal Composition Of Bust/Breast Firming"
153	662/DEL/2008	"Herbal Compositon Of Waist & Tummy Trimming / Firming"
154	155/MUM/2008	Herbal Extract And Ayurvedic Composition For The Treatment Of Diabetics
155	2154/ MUMNP/2007	A Method Of Preparing A GUGGUL Derivative

156	1711/DEL/2007	An Improved Process For The Isolation Of 2,5-Dihydroxy-1, 4-Benzoquinone Derivatives Like Embelin From Natural Resources
157	1675/DEL/2007	"A Non-Invasive Device Nadi Tarangini Useful For Quantitative Detection Of Arterial 'Nadi' Pulse Waveform"
158	1567/CHE/2007	A Process For Nymphayol[17-(Hexan-2yl)-10,13-Dimethylhexadecahydro-1H-Cyclopenta[A] Phenanthren-3-Ol] From Nymphaea Stellata With Antidiabetic Property
159	960/CHE/2007	An Organoleptically Enhanced Salacia Plant Extract And A Process Thereof
160	809/CHE/2007	A Process For Preparation Of A Novel Compound, 6-(1-(10,13-Dimethyl-4, 5,8,9,10, 11, 12,13 ,14,15,16,17-Dodecahydro-1h-Cyclopenta[A] Phenanthren-17-Yl)Ethyl)-3-Methyl-3,6-Dihydro-2h-2-Pyranone From Elephantopus Scaber L. Whole Plant With Antibacterial And Antidiabetic Activity.
161	421/MUM/2007	Auto Enema Apparatus
162	407/MUM/2007	A Tea Composition
163	393/CHE/2007	"A Method Of Removing Waste And Manufacturing Cowdung In Powder And Cake Form"
164	368/CHE/2007	A Novel Kit For Authentication Of Naturally Occurring Raw Drugs And Finished Products And Semi-Quantification Of Bioactive Markers
165	2239/CHE/2006	Processed Tender Coconut Ball
166	1620/MUM/2006	A Process For The Preparation Of An Herbal Skin Ointment
167	1514/MUM/2006	Pellets Of Herbal Extracts And Process For Preparing The Same
168	1651/CHE/2006	Patent of addition
169	855/MUM/2006	A Process For Preparation Of A Polyherbal Composition And The Product Thereof
170	755/MUM/2006	Bioactive Compositions Of Oil Containing Particles Smaller Than One Micron And Process Of Preparation Thereof
171	900/DEL/2006	"A Process For The Preparation Of Potential Antiulcer Compounds From Ginger (Zingiber Officinale) Rhizome "

172	478/MUM/2006	Herbal Composition Comprising Extract Of Root Of <i>Murraya Koenigii</i> For Treatment Of Infections Caused By Dermatophytes
173	1039/ DELNP/2006	"A Pressure Vessel Unit For Cyclic Variations In Altitude Conditioning"
174	56/KOL/2006	A Process Of Preparing Herbosomes With Andrographolide Having Better Hepatoprotective Activity And Product Thereof.
175	3207/DEL/2005	An Ayurvedic Composition For Joining Fractured Bone & As Anti-Inflammatory And Process For Preparation Thereof
176	1267/ MUMNP/2005	A Synergistic Composition For The Treatment Of Diabetes And A Process Thereof
177	1342/ MUM/2005	A Dosage Form Containing Power Of Nut Kernel Of <i>Caesalpinia Bonduc</i> (L.)Roxb. And Process Of Its Preparation
178	1330/ MUM/2005	A Process For Preparation Of A Triherbal Formulation For Treatment Of Bronchial Asthama & Product Thereof
179	1469/CHE/2005	Anti-Stress Herbal Formulation And Process For The Preparation Thereof
180	929/KOL/2005	A Process Of Preparing A Herbal Composition For The Management Of Insomnia/Strees And Product Thereof
181	3320/ DELNP/2005	"Novel Nitrile Glycoside Useful As A Bio-Enhancer Of Drugs And Nutrients"
182	952/CHE/2005	A Process Of Manufacture Of An Ophthalmic Preparation, An Eye Drop From Naturally Occurring Substances For Treating Certain Ailments Of Human Eye
183	1477/ CHENP/2005	A Process For Producing Enriched Fractions Containing Upto 100% Of Bacoside A And Bacoside B From Plant Materials Of <i>Bacopa</i> Species
184	726/CHE/2005	An Ayurvedic Medicine For Curing Viral Hepatitis And The Like Diseases.
185	688/MUM/2005	A Topical Semisolid Silver Nanoparticle Dispersion Formulation
186	356/KOL/2005	A Process For The Preparation Of Herbal Medicine And Product Thereof

187	988/DEL/2005	"Herbal Formulation Useful For Controlling Body Weight "
188	989/DEL/2005	"A Synergistic Aphrodisiac Herbal Composition "
189	794/DEL/2005	"An Improved Process For The Isolation Of Withaferin-A From Plant Materials"
190	391/MUM/2005	A Joss Stick And A Method Of Making The Same
191	1272/ DELNP/2005	An Anti Arrhythmic Compound Designated As Kcv-Caf Obtained From The Venom Of Indian Snake King Cobra Ophiophagus Hannah
192	1261/ DELNP/2005	Novel Herbal Composition As Memory Enhancer In Alzheimers Condition
193	1266/ DELNP/2005	"Dental Care Herbal Formulation And Its Preparation Thereof"
194	380/MUM/2005	A Planetary Joss Stick Prepared In A Bronze Vessel
195	385/MUM/2005	A Joss Stick And A Method Of Making The Same
196	313/CHE/2005	An Unique Combination Of Ayurvedic Compounds For Correcting A Rare Form Of Mullerian Dysgenesis
197	531/DEL/2005	" Fulvic Acid As A Novel Complexing Agent And A Process Of Extraction Thereof"
198	532/DEL/2005	"Fulvic Acids And Humic Acids As Novel Complexing Agents And A Process Thereof"
199	31/MUM/2005	An Ayurvedic Herbal Composition For Treatment Of Cancer/Skin Blood Relateddiseases And Process Of Making Thereof
200	1375/ MUM/2004	Sprayable Synergistic Polyherbal Insecticidal Compositions And A Method For Preparation Thereof
201	1376/ MUM/2004	Herbal Insect Repellent Composition And Process Of Preparation Thereof
202	2504/DEL/2004	"Anticigarette Herbal Formulation As An Anti-Dote To Tobacco"
203	2507/DEL/2004	Development Of Harbal Nutritious Chocaeate And Its Processing
204	2351/DEL/2004	"A Process For The Isolation Of New Protein (Indin-Saa) From Roots Of Boerhaavia Diffusa Linn.(Santh)"
205	2152/DEL/2004	"A Process Of Seperting A Compound Containing Allylisothiocynate From Mustard Seed"
206	2838/ DELNP/2004	"An Improved Process For The Preparation Of Lipid Soluble Extract From Curcuma Species"

207	971/MUM/2004	Process Of Recovery Of Pure Curcumins From Turmeric Rhizomes
208	2610/DELNP/2004	Process For Preparing Stable Bacosites Enriched Fraction In Non-Hygroscopic Form
209	2131/DELNP/2004	A Health Protective Herbal Soft Drink
210	713/CHE/2004	A Novel Herbal Food Composition For Overcoming Iron Deficiency In Anemic Patients
211	700/MUM/2004	A Test Rig For Detecting Missing Components In Engines And A Method For Testing Engines For Detecting Missing Components
212	1641/DELNP/2004	A Herbal Health Drink Composition
213	386/CHE/2004	"A Composition Of Herbal Extracts For Promoting Growth And Development"
214	389/MUM/2004	A Method For Simultaneous Preparation Of Jasad Bhasma And Rasasindoor.
215	585/DEL/2004	A Process For The Preparation Of Antioxident From Black Cumin (Nigella Sativa.) Seeds
216	476/DEL/2004	A Media Composition For Effective Field Establishment Of Decalepis Hamiltonii
217	500/DELNP/2004	Herbal Composition And Its Preparation Thereof
218	00494/DELNP/2004	A PROCESS FOR ISOLATION OF A-GLUCOSIDASE INHIBITORY AGENT
219	377/DELNP/2004	Novel Synergistic Herbal Composition As Brain Tonic And Method For Preparation Thereof
220	122/CHE/2004	A Novel Synergistic Herbal Formulation For Diabetes Cure
221	195/DEL/2004	A Novel Dental And Gum Care Herbal Composition
222	196/DEL/2004	"A Herbal Composition Useful For The Treatment Of Whooping Cough, Reducing Cholesterol & Body Fat"
223	1609/DEL/2003	"Novel Yeast Strains Having Accession No. Drf-Uds 004/Wf And A Method For Propagation Thereof"
224	1524/DEL/2003	"A Herbo-Mineral Formulation"
225	1340/DEL/2003	Novel Herbal Composition For The Treatment Of Gastric Ulcer

226	1048/ MUM/2003	Ayurvedic Immuno-Modulator Composition For Treatment Of Acquired Immuno Deficiency Syndrome
227	1028/ MUM/2003	"A Novel Swertiamarin Compound And Method Of Isolation Of Swertiamarin Form Plant Enicostem Littorale And Its Anti Diabetic Activity"
228	737/CHE/2003	Method Of Isolating A 2-Cysteine Peroxiredoxin Nucleotide Sequence & Uses Thereof
229	943/MUM/2003	Process For The Prepatation Of Ayurvedic Immuno Modulator Composition For Treatment Of Aids
230	944/MUM/2003	Process For The Preparation Of Ayurvedic Antiretroviral Composition For Treatment Of Aids
231	896/MUM/2003	Extract Of Pericarp Of The Fruit Sapindus Trifoliatus Comprising Saponin
232	1232/ DELNP/2003	"A Synergistic Composition Useful For Hepatocurative Action Against Cyp 450 Bio-Activation Mediated Hepatotoxicity, Induced By One Or More Drugs"
233	753/MUM/2003	A System For Complete Spectrum Of Nadi Pulses As A Time Series
234	934/DEL/2003	"A Process Of Dyeing And Processing A Garment."
235	717/DEL/2003	"A Process Of Preparing A Synergistic Herbal Ayurvedic Ointment "
236	402/CHE/2003	"A Process For Preparing Highly Water Soluble Alkeline Earch And Alkeli Metal Double Salts Of Hydroxycitric Acid
237	00483/ DELNP/2003	"A System Detection And Identification Of Principles From Extracts Of Plants Or Animal, Natural Or Synthetic Sources, Using Chromatographic Finger Printing Techniques"
238	266/CHE/2003	Process For Making Palatable Biscuit Formulation Of Chyavanaprasham Confection
239	266/MAS/2003	The Novel Process For Making Palatable Biscuit Formulation Of Chyavanaprasham Confection
240	439/DEL/2003	A Process For Production Of 2-Hydroxy-4-Methoxy Benzaldehyde From Tubers Of Decalepis Hamiltonii Wight & Arn.
241	257/DEL/2003	"A Process For The Preparation Of An Extract And Bio-Active Fractions From Cuminum Cyminum And Composition Therefrom"

242	229/MUM/2003	Method Of Preparing Herbal Composition For Diabetic Patient
243	230/MUM/2003	Process For Manufacturing Of Herbal Food Supplement(Iqtone) For Brain Health Disorders
244	129/DEL/2003	"A Composition Useful For Hepatoprotection"
245	100/MUM/2003	A Method Of Preparing Bioactive Extracts From Biomass
246	1118/ MUM/2002	A Process For Preservation Of Ghee In Pharmaceutical, Ayurvedic, And Neutraceutical Formulations"
247	854/MUM/2002	An Apparatus Allowing The Treatment Of Human Being Using Ayurvedic System Of Treatment
248	969/DEL/2002	A Process For Preparation Of Herbal Formulation Useful For The Treatment Of Diabetes
249	779/MUM/2002	A Process For Herbal Extraction Of Saponins From Sapindus For Anticonvulsant Activity
250	337/DEL/2002	A Process For The Preparation Of Soup Powder Formulation Based On Indian Gooseberry (Phyllunthus Emblica)"
252	200/DEL/2002	"An Improved Process For The Production Of Dry Aqueous Extract Of Vijasar (Pterocarpus Marsupium)"
253	59/CAL/2002	Improved Process For The Preparation Of Drug From The Seeds Of Caesalpinia Bonducella For The Treatment Of Type 2 Diabetes Mellitus
254	486/MAS/2001	Avalmic-I Herbal Based Drug Capsule Preparation
255	487/MAS/2001	A Novel Herbal Drug Composition And Process The Preparation Thereof
256	636/DEL/2001	"A Synergistic Composition Useful For Management of Asthama "
257	123/DEL/2001	"A Process For The Preparation Of A Herbal Mineral Preparation For General Immunity And Strengthening Of Children"
258	1148/DEL/2000	"Process For Preparing Improved Hair Care And Conditioning Composition"
259	488/MUM/2000	A Synergistic Aqueous Pharmaceutical Composition For Prophylactic Treatment Of Migraine
260	478/DEL/2000	"A Novel Herbal Composition For Diabetic Patients And A Process For Producing The Same"

261	158/MAS/2000	A Herbal Composition Having Anti Allergic Properties And A Process For The Preparation Thereof
262	41/DEL/2000	"A Novel Method For Preparation Of Herbal Formulations"
263	1071/MAS/1998	A Process For Making A Composition Containing A Pharmacologically And/Or Biologically Active Plant Extract
264	79/MAS/1998	A Method Of Preparing A Herbal Hepatoprotective And Antihepatotoxic Composition
265	1985/MAS/1997	A Process Of Preparing A Soluble Double Metal Salt Of Group Ia And Iia Of (-) Hydroxycitric Acid
266	1986/MAS/1997	A Process Of Preparing A New Soluble Of (-) Hydroxycitric Acid From Garcinia Extracts

Source: <https://ipindiaservices.gov.in/PublicSearch/PublicationSearch/Search>

Annexure 2: Yoga related Patents granted (48)

Sl. No.	Application Number	Title
1	202121038548	Breathing Exercise Machine
2	202027045217	Bio-Based Eva Compositions And Articles And Methods Thereof
3	202027045216	Bio-Based Elastomeric Eva Compositions And Articles And Methods Thereof
4	201921018475	A System And Method To Provide Skill/Talent Development Connectivity Solutions Nearby To Users
5	201927016922	Point Of Care Assays
6	201911008437	Method And System For Assisting A User In Performing A Pre-Defined Physical Exercise
7	201941005350	System And Non-Intrusive Method For Exercise Posture Detection
8	201911004350	“Computer Vision And Artificial Intelligence-Based Action Identification, Biomechanical Analysis And Pose Estimation Method”
9	201847023149	Controlling A Lighting System
10	201847022966	Controlling A Lighting System
11	201821007794	Rotating Exercise Equipment
12	201841006784	System And Method To Monitor An Exercise Posture Of At Least One User
13	201821004235	Nicotine – Free Smoking Compositions As Well As Nicotine Containing Smoking Compositions Based On Panchagavya With The Combination Of Herbal Leaves
14	201741036569	System And Method For Creating An Environment For Rejuvenating The Degenerated Organs Of A Human
15	201747030988	Portable Light Source
16	201741005871	A Method Of Preparation Of Coffee Leaves Beverages Product
17	201731001942	Herbal Preparation For Therapeutic And Prophylactic Management Of Neurological Disorders
18	2429/MUM/2015	System And Method For Pain Remedy And Rehabilitation

19	1136/ MUMNP/2013	System And Method For Using A Knowledge Representation To Provide Information Based On Environmental Inputs
20	3680/DEL/2012	A Novel Sugar Free Asava Formulation And Process Of Preparation Thereof
21	1660/MUM/2012	A Computer Implemented System And Method For Facilitating Selection Of Bedding Products
22	601/MUM/2012	"Pellets Of Herbal Extracts And Process For Preparing The Same"
23	2039/MUM/2010	A Herbal Composition (Fc) For The Treatment Of Cervical Cancer
24	114/DEL/2010	A Novel Process Of Dyeing And Processing A Natural Textile Product Using Natural Dyes Alongside Neem And Tulsi
25	2632/MUM/2009	Composition For Relieving Stress
26	5522/ CHENP/2009	"Organosilane-Nonionic-Water Stable Quaternary Ammonium Compositions And Methods"
27	2004/MUM/2009	System Beneficial In Improving Health Conditions
28	1373/DEL/2009	"Method Of Providing Customized Caller Tune Via Mobile Terminal And A System Thereof"
29	1379/MUM/2009	A Medical Magnet Therapy Device With The Swinging Movements From Head To Feet Direction
30	465/DEL/2009	"System And Method For Brand-Promotion Through Phone/Mobile Technologies"
31	4639/ CHENP/2007	Methods And Devices For Relieving Stress
32	1675/DEL/2007	"A Non-Invasive Device Nadi Tarangini Useful For Quantitative Detection Of Arterial 'Nadi' Pulse Waveform"
33	1514/MUM/2006	Pellets Of Herbal Extracts And Process For Preparing The Same
34	3300/ CHENP/2006	A Seating Device For Supporting A User Sitting In A Cross Legged Yoga Position
35	522/DEL/2006	A Pharmaceutical Composition For The Prevention/ Treatment Of Bone Disorders And A Process For The Preparation Thereof
36	1039/ DELNP/2006	"A Pressure Vessel Unit For Cyclic Variations In Altitude Conditioning"
37	1469/CHE/2005	Anti-Stress Herbal Formulation And Process For The Preparation Thereof

38	1261/ DELNP/2005	Novel Herbal Composition As Memory Enhancer In Alzheimers Condition
39	1286/ DELNP/2005	Development Of Novel Herebal Formulation Used As An Anti-Diabetic On Traditional Indigenous Knowledge
40	313/CHE/2005	An Unique Combination Of Ayurvedic Compounds For Correcting A Rare Form Of Mullerian Dysgenesis
41	3501/ DELNP/2004	"A Herbal Composition Useful For Gastro-Intestinal Disorders & Process Thereof"
42	1609/DEL/2003	"Novel Yeast Strains Having Accession No. Drf-Uds 004/Wf And A Method For Propagation Thereof"
43	1253/DEL/2003	A Method For Preparation Of A Drug For Curing Asthma
44	486/MAS/2001	Avalmic-I Herbal Based Drug Capsule Preparation
45	487/MAS/2001	A Novel Herbal Drug Composition And Process The Preparation Thereof
46	158/MAS/2000	A Herbal Composition Having Anti Allergic Properties And A Process For The Preparation Thereof
47	41/DEL/2000	"A Novel Method For Preparation Of Habal Formulations"
48	79/MAS/1998	A Method Of Preparin A Herbal Hepatoprotective And Antihepatotoxic Composition

Source: Author's compilation.

Annexeure 3: Unani (80)

Sl. No.	Application Number	Title
1	202011007071	A Polyherbal Unani Formulation Majoon Suranjan Effective Against Cancer Cells Alone As Well As In Combination With Anticancer Durg Sorafenib.
2	201921014684	An Effervescent Herbomineral Composition For Prevention And Therapeutic Management Of Acidity And Methods Of Preparation Thereof
3	201911007661	Broad Spectrum Sun Protective Topical Formulation
4	201741033167	A Synergistic And Non-Toxic Combination For Treating Liver Disorders
5	201741030554	"Process For The Preparation Herbal Drinking Water"
6	201721016134	One Pot Synthesis Of Photo-Active Bimetallic Cupd Quantum Dots With Its Antimicrobial Activity.
7	201731001942	Herbal Preparation For Therapeutic And Prophylactic Management Of Neurological Disorders
8	201621020826	Pharmaceutical Composition To Eliminate Hiv Virus
9	201621005051	Pharmaceutical Compositions
10	201641001693	A Process For The Production Of Alkyl Coumarate Concentrate From Ipomoea Carnea Subsp. Fistulosa
11	630/KOL/2015	Curcumin Infused Milk Beverage And A Process For The Preparation Thereof
12	931/MUM/2014	A Topical Antimicrobial Herbal Formulation
13	999/CHE/2014	Herbal Composition For The Treatment Of Enteritis And Process For Making The Same
14	2625/CHE/2013	Novel And Synergistic Composition Of Lecithin And Lysolecithin For Improving Bioavailability And Solubility Of Hydrophobic Compounds And Extracts
15	1284/KOL/2012	Herbal Composition And Medicament For Treating Malaria.
16	3040/MUM/2012	Herbal Composition And Medicament For Treating Malaria
17	2199/MUM/2012	A Process For Preparation Of Herbal Gelatine
18	2019/CHE/2012	Novel Highly Bioavailable, Water Soluble, Sustained Release Nanoformulations Of Hydrophobic Plant Derived Compounds, And Extracts

19	2277/CHE/2011	A Novel Polyherbal Formulation With Multiple Therapeutic Effects As Antidiabetic, Antifatigue, Hepatoprotective And Antioxidant
20	1109/MUM/2011	A Herbal Formulation For Treatment Of Silent Estrus
21	1049/MUM/2011	Herbal Composition And Medicament For Expulsion Of Placenta
22	3538/MUM/2010	Curcumin Monosulphate, Its Salts, Process For Synthesis Thereof And Treatment Of Cancer
23	3256/MUM/2010	"Biotransformation Of Biologically Active Compounds From Medicinal Plants"
24	1942/DEL/2010	"Scar Primers And A Kit For The Authentication Of Unani Drug Senna (Cassia Acutifolia & Cassia Angustifolia) From Its Adulterant (Cassia Tora & Cassia Sophora)".
25	1943/DEL/2010	"Scar Primers And A Kit For The Authentication Of Unani Drug Mulethi (Glycyrrhiza Glabra) And Its Adulterant Abrus Precatorious".
26	1944/DEL/2010	"Scar Primers And A Kit For The Authentication Of Unani Drug Filfil Siyah (Piper Nigrum) And Its Adulterant Carica Papaya".
27	1945/DEL/2010	"Scar Primers And A Kit For The Authentication Of Unani Drug Zarishk (Berberis Aristata) And Its Adulterant Daru Haridra (Cosciniun Fenestratum)".
28	1947/DEL/2010	"Scar Primers And A Kit For The Authentication Of Unani Drug Zaafran (Crocus Sativus) And Its Adulterant Qurtum (Carthamus Tinctorious)".
29	1948/DEL/2010	"Scar Primers And A Kit For The Authentication Of Unani Drug (Rewand Chini) Rheum Emodi And Its Adulterant Rheum Palmatum".
30	1946/DEL/2010	"SCAR Primers For The Authentication Of Unani Drug Zizyphus Jujuba And Its Adulterant Jhad Beri (Zizyphus Nummularia)"
31	2356/CHE/2010	A Pharmaceutical Composition Of Reformulated Turmeric Extract And A Method Thereof
32	1890/DEL/2010	"Scar Primers And A Kit For The Authentication Of Unani Drug Amla (Embllica Officinalis) And Its Adulterant Shakarkand (Ipomeae Batatas)"
33	774/DEL/2010	"A Process For The Preparation Of Bio-Active Sub-Fraction From Flowers Of Simarouba Glauca Active Against Filariasis"

34	114/DEL/2010	A Novel Process Of Dyeing And Processing A Natural Textile Product Using Natural Dyes Alongside Neem And Tulsi
35	1736/DEL/2009	"Scar And A Kit For The Authentication Of Single Drug Tukhm-E-Kasoos (Cuscuta Reflexa) And Its Adulcrant Aftimoon Vilayati (Cuscuta Chinensis)"
36	285/DEL/2009	"A Process For Preparation Of Oleoresins From Seed Spices Using Cell Degrading Enzymes"
37	165/DEL/2009	"A Synergistic Herbal Composition For Lowering Blood Glucose And Blood Cholesterol Levels"
38	1882/DEL/2008	"A Method Of Preparing New Anti Cancer Herbal Medicine And Product There Of"
39	1146/ MUM/2008	Device For Stripping Curry Leaf
40	662/DEL/2008	"Herbal Compositon Of Waist & Tummy Trimming / Firming"
41	1567/CHE/2007	A Process For Nymphayol[17-(Hexan-2yl)-10,13-Dimethylhexadecahydro-1H-Cyclopenta[A] Phenanthren-3-Ol] From Nymphaea Stellata With Antidiabetic Property
42	960/CHE/2007	An Organoleptically Enhanced Salacia Plant Extract And A Process Thereof
43	809/CHE/2007	A Process For Preparation Of A Novel Compound, 6-(1-(10,13-Dimethyl-4, 5,8,9,10, 11, 12,13,14,15,16,17-Dodecahydro-1h-Cyclopenta[A] Phenan Thren-17-Yl)Ethyl]-3-Methyl-3,6-Dihydro-2h-2-Pyranone From Elephantopus Scaber L. Whole Plant With Antibacterial And Antidiabetic Activity.
44	368/CHE/2007	A Novel Kit For Authentication Of Naturally Occurring Raw Drugs And Finished Products And Semi-Quantification Of Bioactive Markers
45	2114/ MUM/2006	A Medicament For The Treatment Of Hiv Infection,
46	1644/ MUM/2006	Body Massage Oil
47	1620/ MUM/2006	A Process For The Preparation Of An Herbal Skin Ointment
48	1862/DEL/2006	"A Novel Herbal Composition And A Process For Preparation Thereof Effective Against Constipation"

49	214/DEL/2006	"A Novel Herbal Composition (Sugar Coated) Effective Against Rheumatoid Arthritis."
50	215/DEL/2006	""A Herbal Composition Effective Against Nazfuddam And A Process For The Preparation Thereof"
51	218/DEL/2006	"A Novel Herbal Composition Effective Against Coryza And A Process For Preparing Thereof "
52	219/DEL/2006	"A Novel Herbal Composition Effective As Anit Pyretic And To A Process For The Preparation Thereof"
53	1267/ MUMNP/2005	A Synergistic Composition For The Treatment Of Diabetes And A Process Thereof
54	1342/ MUM/2005	A Dosage Form Containing Power Of Nut Kernel Of Caesalpinia Bonduc(L.)Roxb. And Process Of Its Preparation
55	1469/CHE/2005	Anti-Stress Herbal Formulation And Process For The Preparation Thereof
56	952/CHE/2005	A Process Of Manufacture Of An Ophthalmic Preparation, An Eye Drop From Naturally Occurring Substances For Treating Certain Ailments Of Human Eye
57	988/DEL/2005	"Herbal Formulation Useful For Controlling Body Weight "
58	989/DEL/2005	"A Synergistic Aphrodisiac Herbal Composition "
59	794/DEL/2005	"An Improved Process For The Isolation Of Withaferin-A From Plant Materials"
60	1272/ DELNP/2005	An Anti Arrhythmic Compound Designated As Kcv-Caf Obtained From The Venom Of Indian Snake King Cobra Ophiophagus Hannah
61	1261/ DELNP/2005	Novel Herbal Composition As Memory Enhancer In Alzheimers Condition
62	531/DEL/2005	" Fulvic Acid As A Novel Complexing Agent And A Process Of Extraction Thereof"
63	532/DEL/2005	"Fulvic Acids And Humic Acids As Novel Complexing Agents And A Process Thereof"
64	2504/DEL/2004	"Anticigarette Herbal Formulation As An Anti-Dote To Tobacco"
65	2351/DEL/2004	"A Process For The Isolation Of New Protein (Indin-Saa) From Roots Of Boerhaavia Diffusa Linn.(Santh)"
66	713/CHE/2004	A Novel Herbal Food Composition For Overcoming Iron Deficiency In Anemic Patients

67	551/MUM/2004	“A Method Of Making An Arsenic Free Formulation For Suvarna Bhasma”
68	202/CHE/2004	A Process For The Synthesis Of Pharmacologically Active (Z/E)-Guggulsterones
69	184/MUM/2004	A Process Of Preparing A Herbal Composition For External Application Of Skin Diseases
70	1028/MUM/2003	"A Novel Swertiamarin Compound And Method Of Isolation Of Swertiamarin Form Plant Enicostem Littorale And Its Anti Diabetic Activity"
71	582/DEL/2003	"A Herbal Composition Against Bronchial Asthma And Process For Preparation Thereof"
72	00483/DELNP/2003	"A System Detection And Identification Of Principles From Extracts Of Plants Or Animal, Natural Or Synthetic Sources, Using Chromatographic Finger Printing Techniques"
73	230/MUM/2003	Process For Manufacturing Of Herbal Food Supplement(Iqtone) For Brain Health Disorders
74	221/MUM/2003	Efficient Method Of In-Vitro Microporpagation Of Piper Longum Plants
75	100/MUM/2003	A Method Of Preparing Bioactive Extracts From Biomass

Note: While the total number is shown as 80, the website has list of only 75 granted patents.

Annexure 4: Siddha (54)

Sl. No.	Application No.	Title
1	202121029926	“A Process For Isolating Glycyrrhetic Acid From Glycyrrhiza Glabra”
2	202041040222	A Novel Synergistic Poly-Herbal Composition From 1 To 19 Herbs Prepared Of Extracts Spray(Thermal Fo
3	201911007661	Broad Spectrum Sun Protective Topical Formulation
4	201821004235	Nicotine – Free Smoking Compositions As Well As Nicotine Containing Smoking Compositions Based On Panchagavya With The Combination Of Herbal Leaves
5	201741033167	A Synergistic And Non-Toxic Combination For Treating Liver Disorders
6	201741030554	"Process For The Preparation Herbal Drinking Water"
7	201621020826	Pharmaceutical Composition To Eliminate Hiv Virus

8	201641001693	A Process For The Production Of Alkyl Coumarate Concentrate From Ipomoea Carnea Subsp. Fistulosa
9	1698/DEL/2014	A Synergistic Pharmaceutical Composition For Gastrointestinal Disorders
10	931/MUM/2014	A Topical Antimicrobial Herbal Formulation
11	2625/CHE/2013	Novel And Synergistic Composition Of Lecithin And Lysolecithin For Improving Bioavailability And Solubility Of Hydrophobic Compounds And Extracts
12	1530/MUM/2013	Method For Preparation Of A Herbal Contraceptive Composition
13	4824/CHE/2012	Pharmaceutical Compositions Comprising Costus Igneus Extract
14	1177/KOL/2012	"An Oral Herbal Extract Composition For Use In Treating Cerebral Malaria"
15	2019/CHE/2012	Novel Highly Bioavailable, Water Soluble, Sustained Release Nanoformulations Of Hydrophobic Plant Derived Compounds, And Extracts
16	2277/CHE/2011	A Novel Polyherbal Formulation With Multiple Therapeutic Effects As Antidiabetic, Antifatigue, Hepatoprotective And Antioxidant
17	1111/CHE/2011	A Synergistic Herbal Extract Composition For Use In Treating Fever In Animals
18	1033/CHE/2011	Veterinary Herbal Compositions For And Medicaments Thereof
19	3538/MUM/2010	Curcumin Monosulphate, Its Salts, Process For Synthesis Thereof And Treatment Of Cancer
20	3256/MUM/2010	"Biotransformation Of Biologically Active Compounds From Medicinal Plants"
21	1942/DEL/2010	"Scar Primers And A Kit For The Authentication Of Unani Drug Senna (Cassia Acutifolia & Cassia Angustifolia) From Its Adulterant (Cassia Tora & Cassia Sophera)".
22	1943/DEL/2010	"Scar Primers And A Kit For The Authentication Of Unani Drug Mulethi (Glycerrhiza Glabra) And Its Adulterant Abrus Precatorious".
23	1944/DEL/2010	"Scar Primers And A Kit For The Authentication Of Unani Drug Filfil Siyah (Piper Nigrum) And Its Adulterant Carica Papaya".

24	1945/DEL/2010	"Scar Primers And A Kit For The Authentication Of Unani Drug Zarishk (<i>Berberis Aristata</i>) And Its Adulterant Daru Haridra (<i>Coscinium Fenestratum</i>)".
25	1947/DEL/2010	"Scar Primers And A Kit For The Authentication Of Unani Drug Zaafran (<i>Crocus Sativus</i>) And Its Adulterant Qurtum (<i>Carthamus Tinctorious</i>)".
26	1948/DEL/2010	"Scar Primers And A Kit For The Authentication Of Unani Drug (Rewand Chini) Rheum Emodi And Its Adulterant Rheum Palmatum".
27	1946/DEL/2010	"SCAR Primers For The Authentication Of Unani Drug Zizyphus Jujuba And Its Adulterant Jhad Beri (<i>Zizyphus Nummularia</i>)"
28	2356/CHE/2010	A Pharmaceutical Composition Of Reformulated Turmeric Extract And A Method Thereof
29	1890/DEL/2010	"Scar Primers And A Kit For The Authentication Of Unani Drug Amla (<i>Emblca Officinalis</i>) And Its Adulterant Shakarkand (<i>Ipomeae Batatas</i>)"
30	960/CHE/2007	An Organoleptically Enhanced Salacia Plant Extract And A Process Thereof
31	368/CHE/2007	A Novel Kit For Authentication Of Naturally Occurring Raw Drugs And Finished Products And Semi-Quantification Of Bioactive Markers
32	1620/MUM/2006	A Process For The Preparation Of An Herbal Skin Ointment
33	478/MUM/2006	Herbal Composition Comprising Extract Of Root Of <i>Murraya Koenigii</i> For Treatment Of Infections Caused By Dermatophytes
34	522/DEL/2006	A Pharmaceutical Composition For The Prevention/ Treatment Of Bone Disorders And A Process For The Preparation Thereof
35	1267/MUMNP/2005	A Synergistic Composition For The Treatment Of Diabetes And A Process Thereof
36	1469/CHE/2005	Anti-Stress Herbal Formulation And Process For The Preparation Thereof
37	952/CHE/2005	A Process Of Manufacture Of An Ophthalmic Preparation, An Eye Drop From Naturally Occurring Substances For Treating Certain Ailments Of Human Eye
38	988/DEL/2005	"Herbal Formulation Useful For Controlling Body Weight "

39	989/DEL/2005	"A Synergistic Aphrodisiac Herbal Composition "
40	531/DEL/2005	" Fulvic Acid As A Novel Complexing Agent And A Process Of Extraction Thereof"
41	532/DEL/2005	"Fulvic Acids And Humic Acids As Novel Complexing Agents And A Process Thereof"
42	2504/DEL/2004	"Anticigarette Herbal Formulation As An Anti-Dote To Tobacco"
43	3501/ DELNP/2004	"A Herbal Composition Useful For Gastro-Intestinal Disorders & Process Thereof"
44	713/CHE/2004	A Novel Herbal Food Composition For Overcoming Iron Deficiency In Anemic Patients
45	386/CHE/2004	"A Composition Of Herbal Extracts For Promoting Growth And Development"
46	389/MUM/2004	A Method For Simultaneous Preparation Of Jasad Bhasma And Rasasindoor.
47	896/MUM/2003	Extract Of Pericarp Of The Fruit Sapindus Trifoliatus Comprising Saponin
48	00483/ DELNP/2003	"A System Detection And Identification Of Principles From Extracts Of Plants Or Animal, Natural Or Synthetic Sources, Using Chromatographic Finger Printing Techniques"
49	100/MUM/2003	A Method Of Preparing Bioactive Extracts From Biomass
50	779/MUM/2002	A Process For Herbal Extraction Of Saponins From Sapindus For Anticonvulsant Activity
51	488/MUM/2000	A Synergistic Aqueous Pharmaceutical Composition for Prophylactic Treatment of Migraine
52	158/MAS/2000	A Herbal Composition Having Anti Allergic Properties And A Process For The Preparation Thereof
53	405/MAS/1999	A Pharamaceutical Formulation for The Treatment of Hepatitis & Viral Infections And A Process For Its Preparation
54	1071/ MAS/1998	A Process for Making a Composition Containing a Pharmacologically And/or Biologically Active Plant Extract

Source: Author's compilation.

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