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## REVIEW ARTICLE

### AYURVEDA AND INTELLECTUAL PROPERTY RIGHTS (IPR)

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#### Abstract:

Growing awareness of Ayurvedic medicines and formulations has led to several conflicts with western pharmaceutical companies who are taking the lead from Ayurvedic medicines and patenting them in their own name. But as we are all aware that the intellects involved behind constructing this unique science is very much grass rooted in India and the country is responsible for producing the majority of Ayurvedic leads right from the traditional times. An overview of understanding the concept, rules, laws, regulations, present status, controlling authorities with emphasis on its statistical inference to understand the future challenges of Intellectual Property Rights and how to restore our scientific knowledge to promote ideas and make them acceptable without financial constraints. Evaluating and reviewing the terms, criteria's included in IPR. The outcome is pretty much predictable that we need rules, proper structured laws to protect our patents, our natural resources and for proper understanding of IPR courses conducted on it should be increased. Considering the statistical aspects the execution of IPR has decreased over the years due to lack of systematic indulgence in traditional system of medicine. The number of governing bodies included has expensive and strict vigilances that decrease the promotion of ideas from the mass people as they are very few governing bodies. A proper council easily understandable and approachable is of utmost importance.

**Keywords:** Ayurveda, Intellectual property rights, IPR, Patent medicine, Courses, Financial status of Ayurveda

#### Introduction:

Ayurveda is the science of life, prevailing from the time of human existence and which is very much grass rooted in the Indian traditional system of science. Thus to preserve and nurture this unique system of science, the intellects thriving their ideas must be protected to justify their knowledge for further advancements. Such a system that would ensure development in the field of Ayurveda is Intellectual property rights. Intellectual property (IP) is a term referring to a number of

distinct types of expressions for which a set of rights are recognized under the corresponding fields of law.<sup>1</sup> Common types of intellectual property rights include copyrights, trademarks, patents, industrial design rights, and trade secrets in some jurisdictions. Laws and concepts behind copyright and patents are not new, the term intellectual property is relatively recent, dating from the 19th century.<sup>2</sup> Ayurvedic lead compounds must be shelled until and unless they are introduced in the market by enforcing intellectual property rights. The Indian Patent Office has received a

number of applications from Indian as well as foreign inventors and companies seeking patents in all fields of technologies, including possibly Ayurvedic medicines, which are published on the website of the Patent Office, namely,<sup>3</sup>

The term Intellectual property is defined in the WIPO convention to include rights relating to, literary, artistic and scientific works, performances of performing artists, sound recordings, and broadcasts; inventions in all fields of human endeavor; scientific discoveries; industrial designs; trademarks, service marks, and commercial names and designations; protection against unfair competition; and, all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic field.<sup>4</sup> Although many of the legal principles governing intellectual property rights have evolved over centuries, it was not until the 19th century that the term intellectual property began to be used, and not until the late 20th century that it became commonplace in the majority of the world.<sup>5</sup> The British Statute of Anne 1710 and the Statute of Monopolies 1623 are now seen as the origin of copyright and patent law respectively.<sup>6</sup>

### **Methods and methodologies**

#### **Guidelines for controlling a proper IPR:<sup>7</sup>**

a) To make scientists aware that all inventions and discoveries made during the course of their employment will belong to the council that is concerned in establishing it. Any discovery or invention carried in whole or in part or under the direction of any staff of the council, which is supported by the council or by funds controlled or administered by the council shall belong to the council.

b) All inventions must be disclosed properly to the council by all staff of the council to begin the process of protecting, patenting and transferring. The invention need not be complete when staff first informs the council. Additional information can be added to as it is developed until the invention is completed and a working title for the invention is given.

c) The authority to manage inventions and discoveries including technology knows how that may be licensable but may not be patented is vested to the director of that council. The director may delegate this authority under this policy to any other person in the council as per need to evaluate and obtain patent as deemed necessary. Such inventions are to be assigned to council for commercialization.

d) Council will utilize all of its IPs itself. In case council is interested in commercialization of a particular IP it will transfer the IP to interested parties by way of licensing.

e) In the event council commissions others, or is commissioned by others, to engage in cooperative research and development of technologies, ownership of IP derived from those research and development projects shall be determined by the respective cooperation contract.

#### **2).Objectives of IPR:**

The stated objective of most intellectual property law (with the exception of trademarks) is to "Promote progress."<sup>8</sup> By exchanging limited exclusive rights for disclosure of inventions and creative works, society and the patentee/copyright owner mutually benefit, and an incentive is created for inventors and authors to create and disclose their work. Some commentators have noted that the objective of intellectual property legislators and those who support its implementation appears to be "absolute protection." "If some intellectual property is desirable because it encourages innovation, they reason, more is better. The thinking is that creators will not have sufficient incentive to invent unless they are legally entitled to capture the full social value of their inventions." <sup>9</sup>This absolute protection or full value view treats intellectual property as another type of 'real' property, typically adopting its law and rhetoric. Other recent developments in intellectual property law, such as the America Invents Act, stress international harmonization. Trademark law is not based in the intellectual property clause of

the U.S. Constitution, and has distinct policy objectives which are not discussed here

3) **Ayurveda and IPR (Controversy)**<sup>10</sup>: Growing awareness in the West of the efficacy of Ayurvedic herbs and formulations has led to controversy and battles with the Western pharmaceutical companies trying to patent these herbs. Only recently discovered in the West, Ayurvedic herbs such as *Neem*, *Ashwagandha*, *Tulsi*, *Shatavari*, *Turmeric*, *Amalaki* and *Brahmi* as well as traditional preparations such as *Triphala* and *Trikatu* have long been known to have significant medicinal value without adverse side effects. Several pharmaceutical companies and academic institutions in the West have come into conflict with Indian academic institutions and traditional Ayurvedic practitioners over the intellectual property rights of herbal products researched by the Western agencies. The Ayurvedic practitioners have known about the efficacy of such products for centuries, and so contend that they carry precedence with regards to patent rights on such products.

“Indian farmers, traditional practitioners, and traders will lose their market share in local, national and global markets. For example, recently the U.S. government granted a patent for the anti-diabetic properties of *karela*, *jamun*, and *brinjal* to two non-resident Indians, Onkar S.Tomer and Kripanath Borah, and their colleague Peter Gloniski. Yet the use of these substances for control of diabetes is everyday knowledge and practice in India. Their medical use is documented in authoritative treatises such as *Wealth of India*, the *Compendium of Indian Medicinal Plants* and the *Treatise on Indian Medicinal Plants*.

#### 4. Terminologies related to IPR<sup>11</sup>:

a) **Copyright**: Copyright is the exclusive right given by law to the creators of literary, musical and artistic worlds, films and records. The creators of literary works and artistic works such as writer, poets, composers of music and artists have rights of ownership of their works. These rights are afforded legal protection to prevent unlawful re-protection of such works.

The object of the Copyright Act is to protect the writer and the artist from unlawful re-production, plagiarism, piracy and imitation. However, production of an identical item through independent creative research is not prohibited and there can be no liability for infringement in such cases. The law in essence is concerned with the negative right of preventing the copyright of physical material, existing in the field of literature and art. The copyright enables the author to claim authorship of the work as well as to restrain or claim damages in respect of distortion or other modifications in the work or any other action which is prejudicial to his honor or reputation in relation to that work. While in case of patents, designs and trademarks, the rights can be acquired only by registration, in case of copyright registration is not necessary and it subsists automatically. Like all the intellectual property rights, copy rights protection as obtained by the domestic law of a country and the adequacy of the present copyright Act, 1957.

b) **Trade Marks Law**: When a person gets his trade mark registered under law, he acquires valuable rights by reason of such registration. Registration of his trade mark gives him the exclusive right to the use of the trade mark in connection with the goods in respect of which it is registered and if there is any invasion of this right by any other person using a mark which is the same or deceptively similar to his trade mark, by an action for infringement in which he can obtain injunction, damages, or an account of profit made by the other person.

c) **Geographical Indication**: Certain geographical names have acquired a lot of importance in the commercial market, particularly with regard to the goods uniquely associated with such names.

In respect of any agricultural goods, natural goods or manufactured goods, or any goods of handicraft or goods of industry including food stuff, generally, bears the geographical indications to attract the attention of the consumers. Traders attach considerable value

to the public recognizing the source, particularly the place of origin of the goods, especially when the name of that place is taken as a synonym necessarily after long and continuous use, for some special quality associated with the product originating from that place. Example is: *Darjeeling tea*, *Kanjevaram silk*, etc. There is every possibility of misusing such geographical names and wrongly applying to even those goods or products, not associated with such names. Persons producing such articles will, justifiably, claim an exclusive right to use such geographical appellations in the description of their products, which implies that they would seek to prevent traders producing those goods elsewhere.

d) **Design of an IPR:** A design is something which is applied to an article and is not the article itself. An article to which the design is to be applied must be something which is to be delivered to the purchaser as finished goods. The buildings and structure are not articles within the definition of design. But portable structures or models which are sold as finished articles may subject matter for registration of design. Design right is a new intellectual property right which applies to original, non-common place designs of the shape or configuration of articles. It is not a monopoly right but a right to prevent copying and lasts until five years from the date of registration, which is extendable for a further period of five years, and for another period of five years on payment of requisite fee. A design right is a property, which like any other business commodity, may be bought, sold or licensed. All applications for registration of design are to be made to the controller of patents by a person claiming to be proprietor to the design. There are four features relevant to an industrial or product design. They are shape, configuration, pattern and ornament. The shape and configuration refer to the form of an article and is usually three dimensional in nature. Pattern and ornament are decorative features ordinarily applied to be surface of the article and they are in the nature of two-dimensional. The design refers to features of

shape which appeal to the eye should be judged solely by the eye and not by any functional considerations. A design in order to be registered must be both new and original and not previously published. The words 'new' or 'original' involves the idea of novelty either in the pattern, shape, or ornament itself. In deciding the question of novelty or originality evidence of experts in the trade is admissible. The design for registration should not be published previously. Publication may be of two types –

- i) Publication in prior documents, and
- ii) Publication by prior use.

e) **Patent:** A patent is a legal monopoly granted to the owner of a new invention which is capable of use, for a limited period of time. It is a statutory privilege granted by the Government to inventors and other persons deriving their rights from the inventor; Under patent system, useful proprietary knowledge moves physically across borders constantly. Under the concept of exclusive right, an inventor may exclude all others from the manufacture, use and sale of a qualifying invention. With regard to the duration of the exclusive right, there is a length of time, whether fixed, adjustable, renewable or indefinite. In some cases, the patent life may be for 17 to 20 years. A patent is a form of industrial or intellectual property. A patent being a creation of statute is territorial in extent. A patent granted in one state cannot be enforced in another state unless the invention concerned is also patented in that state. Mainly states that the concept of patent and its essential ingredients like novelty, invent step, lack of obviousness and sufficiency of description have remained the same ever since was conceived over four hundred years ago. A patent is not granted for an idea or principle as such, but for some article or the process of making some article. A patent is to encourage and develop new technology and industry. An inventor has exclusive right to keep it secretly. The patent is granted for a statutory period and after the expiry of monopoly period others can use the invention or improve upon it. Patents

have assumed an international character. The international convention for the protection of Industrial Property (i.e., Paris Convention) and the TRIPS Agreement of WTO provided patent rights for industrial property in all the countries of the union for the protection of industrial property. In India, the rights conferred on a patentee are purely

Statutory rights conferred by the Patent Act 1970 and as amended from time to time. India has had a patent system since 1856, and the present Patent Act, 1970 is a successor to the Indian Patent and Design Act, 1911. The 1970 Act made a significant departure from the previous Act in removing the scope in the 1911 Act for obtaining product patents for drugs and medicines and certain classes of chemicals, by expressly prohibiting, through section 5 of the Act, as it stood before the 1999 Amendment, the issue of a patent in respect of claim for the substance itself where:

- (i) The invention claimed that the substance was one intended for use, or capable of being used, as food or as medicine or drug, or
- (ii) The invention related to a substance prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and intermetallic compounds.

**f) Undisclosed Information (Confidential Information):** People in business, trade and manufacture prepare to keep the information relating to their financial management, inventive administrative procedures which contribute to efficiency in production and value addition undisclosed. The disclosure of such information might help his competitors and predators of knowledge. Secrecy and a belief in its efficiency and utility are the factors which make the information undisclosed. If the undisclosed information is already known or is in common use or ceases to be of any utility the information loses its characteristics of undisclosed or confidentiality. The right in undisclosed information is a civil right. It is inherent in every person acquire, retain and protect undisclosed information about his business, trade and manufacture. The Trade Related

Aspects of Intellectual Property Rights (TRIPS) of WTO protects the undisclosed information globally.

**g) Curbing Anti-Competitive Licensing Contracts :**

The owner of a copyright, patent or other form of intellectual property right can issue a license for someone else to produce or copy the protected trademark, work, invention, design, etc. The agreement recognizes that the terms of a licensing contract could restrict competition or impede technology transfer. It says that under certain conditions, governments have the right to take action to prevent anti-competitive licensing that abuses intellectual property rights. It also says governments must be prepared to consult each other on controlling anti-competitive licensing.

**h)CBD:( Convention on Biodiversity)<sup>12</sup>** The convention was opened at the United Nations Conference on Environment and Development in Rio de Janeiro in June 1992. It came into force at the end of 1993 and has now been ratified by the overwhelming majority of countries, for whom it is now a legally binding commitment to conserve biological diversity, to sustainably use its components and to share equitably the benefits arising from the use of genetic resources.

**i)Compulsory Licensing:** If the reasonable requirements of the public with respect to the patented invention have not been satisfied or if the patented invention is not available to the public at a reasonable price, then a prayer for the grant of a compulsory license to work the patented invention can be made. This is done at any time after the expiry of a three years period from the date of the grant of a patent.

**j)GATT(General Agreement on Tariffs and Trade)-** GATT, the organization which was established in 1947 as the organization overseeing the multilateral trade system has been replaced by WTO with effect from January 1, 1995.

**k)IPC.<sup>[31]</sup>** International Patent Classification (IPC) subdivides the whole gamut of technology into different sub-groups and is used by the national patent offices throughout the world in classifying the subject matter

contained in patent documents. Each patent document bears one or more IPC code assigned to it by the respective Patent Office.

l) **Parallel Import:** Parallel imports involve the import and resale in a country, without the consent of the patent holder, of a patented product which was put on the market of the exporting country by the title holder or in another legitimate manner

m) **TRIPS:** Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS 1994); this Agreement constitutes Annex IC of the Marrakesh Agreement Establishing the World Trade Organization, which was concluded on April 15, 1994, and entered into force on January 1, 1995. The TRIPS Agreement binds all Members of the WTO.

n) **TKDL:** Traditional Knowledge Digital Library (TKDL), an Indian initiative, presently aims at documenting and classifying according to IPC, knowledge from traditional systems such as Ayurveda, Unani and Siddha

o) **TKRC:** Traditional Knowledge Resource Classification (TKRC) is the classification evolved to enable retrieval of information on traditional knowledge in a scientific manner so that it can be readily linked to IPC.

p) **WIPO:** World Intellectual Property Organization (WIPO) is an International organization dedicated to promoting the use and protection of works of human intellect and is one of the sixteen specialized agencies of the United Nations System of organization. Presently, 177 nations are its members.

q) **WIPONET:** WIPONET is a global Intellectual Property network set up by WIPO enabling the integration of IP information resources, processes and systems of worldwide Intellectual Property communities, particularly IP offices of the member states.

r) **WTO:**<sup>[31]</sup> World Trade Organization is the only global international organization dealing with the rules of trade between nations. WTO comes into being on January 1, 1995. As one of the youngest international organization, it is a successor to GATT.

5) **Education Regarding IPR**<sup>13</sup>: The

following courses are offered by IIPRM

i) Three months Certificate Program in IPR

ii) Three months Certificate Program in Patent Laws and Practices

iii) Six months Diploma in IPR Law

6) **IPR for Ayurvedic drugs in raw form:**<sup>14</sup>

There are two types of Ayurvedic medicines prepared in the country. First the classical drugs second are the patent and proprietary medicine manufactured by the pharmaceutical industry of the Indian Systems of Medicine on their own developed formulations. Since these crude drugs raw material may not have been evaluated scientifically on botanical, pharmacognostical, chemical and pharmacological parameters it is therefore necessary to screen them out for various ailments. Pharmaceutical industry of ISM in the country is very large and manufacturing its drugs on the basis of license issued by the Drug control authorities of the respective states. Their trade history, supply, demand involvement of national level institutions and their trade market is not properly established. Looking into all these aspects it is necessary that the aspects of IPR and assessment of raw material used in ISM is given top priority. The forum of parliaments on IPR must be executed. The agreement on Trade-Related Aspects of IPR as contained in the final act of the Uruguay Round, seeks to strengthen intellectual property protection in order to promote world trade and rapid economic development.

7) **Traditional Medicine and IPR**

**Perspective:** Traditional Medicine (TM) plays a crucial role in health-care and serves the health needs of a vast majority of people in developing countries. Access to health care services and medicine may be limited in developing countries. TM becomes the only affordable treatment available to poor people and in remote communities. World Health Organization (WHO) defines traditional medicine as the sum total of all the knowledge and practices, whether explicable or not, used in diagnosis, prevention and elimination of physical, mental or social imbalance and

relying exclusively on practical experience and observations handed down from generation to generation, whether verbally or in writing. Health care providers worldwide including major pharmaceutical giants are turning to incorporate many of these into their mainstream activities. As traditional medicines are largely based on medicinal plants, indigenous to these countries, where the system has been in vogue for several centuries, the effort is on accessing them either directly or through the use of modern tools of breeding and cultivation, including tissue culture, cell culture and transgenic technology. IP issues linked to such endeavors remain unresolved.<sup>15</sup>The protection of Traditional Medicine (TM) under intellectual property rights (IPRs) raises two types of issues. First, to what extent it is feasible to protect, existing IPR system. Certain aspects of TM may be covered by patents or other IPRs. Intellectual property is a form of private sovereignty over a primary good-information.<sup>16</sup>

#### **8) Critical Cases Regarding IPR of Ayurvedic Medicines:**

a) **Turmeric Patent Case<sup>17</sup>:** Two US-based Indians Suman K. Das and Hari Har P. Cohly were granted a US Patent 5, 40,504 on 28 March 1995 on Use of turmeric in wound healing. The patent was assigned to University of Mississippi Medical Center, USA. This patent claimed the administration of an effective amount of turmeric through local and oral route to enhance the wound healing process, as a novel finding. Any patent, before it is granted, has to fulfill the basic requirements of novelty, non-obviousness and utility. Thus, if the claims have been covered by relevant published art, then the patent becomes invalid. Council of Scientific and Industrial Research (CSIR) could locate 32 references (some of them being more than one hundred years old and in Sanskrit, Urdu and Hindi), which showed that this finding was well known in India prior to filing of this patent. The formal request for re-examination of the patent was filed by CSIR at United States Patent and Trademark Office (USPTO) on 28 October 1996. On 20 November 1997,

the examiner rejected all the claims once as being anticipated and obvious. The re-examination certificate was issued on this case on 21 April 1998 bringing the re-examination proceedings to a close. The following points are interesting to note:

The turmeric case was a landmark case in that this was the first time that a patent based on the traditional knowledge of a developing country was challenged successfully and USPTO revoked the patent. This eventually opened up the path to the creation of Traditional Knowledge Digital Library, Traditional Knowledge Resource Clarification, and finally inclusion of traditional knowledge in the International Patent Clarification System.

World Intellectual Property Organization (WIPO) has been sensitive to these concerns. At a conference held in October 1998, under the aegis of the WIPO an agenda for the future of IPR in the field of traditional medicines was prepared, which prioritized activities in this area, namely, development of standards for the availability, scope and use of IPRs on traditional medicine in Asian countries, systematic documentation of traditional medicine for protection purposes, regional and inter-regional information exchange and compilation of the requisite databases, etc. This agenda needs to be moved forward.

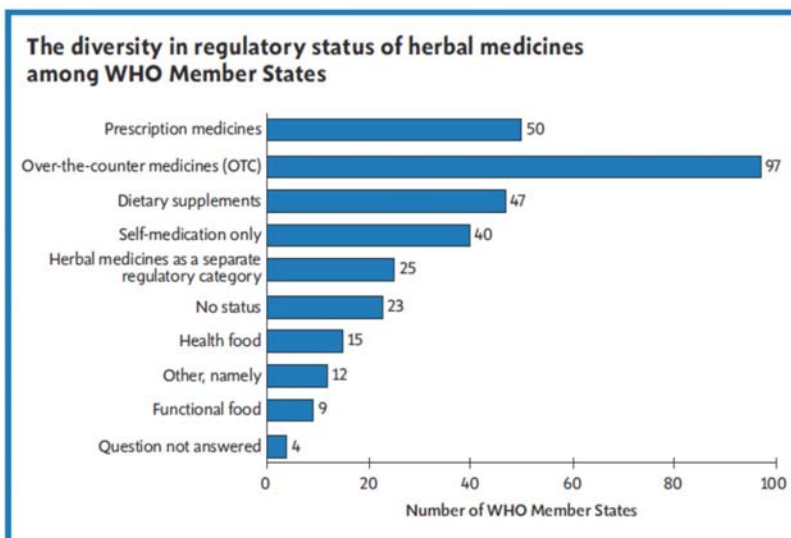
#### **9) Rules and Regulation Regarding IPR of Ayurvedic Medicines:**

i) **Registration of Ayurvedic Medicines:** Traditional medicines are characterized in many different ways throughout the various jurisdictions around the world. They are commonly sold either as a prescription or over the counter (OTC) medicine<sup>18</sup> or may be variously described as self-medication, home remedies, dietary supplements, health foods, functional foods or phytoprotectants, or by some other title. The Canadians, for example, frequently use the term “folk medicines”<sup>19</sup> These types of products are variously marketed under the banner of traditional medicines, herbal medicines, herbal supplements, herbal pharmaceuticals,

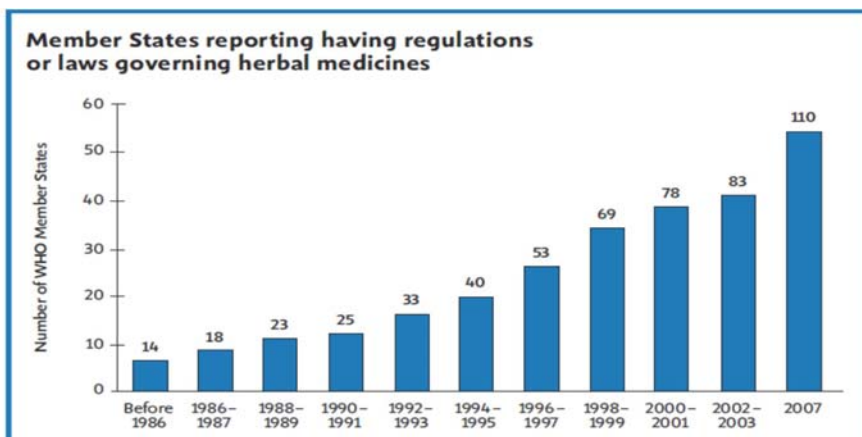
phytoprotectants or phytotherapeutic agents, or even simply as medicines or as a foodstuff<sup>20</sup> The array of classification options for herbal preparations is ably illustrated by the example of *garlic*. *Allium sativum* (*garlic*) is a useful example when trying to understand the complicated regulatory environment for traditional medicines. Garlic is eaten as a food or spice all over the world, but it is also frequently used for health benefit, including to lower blood cholesterol and to inhibit some cancer processes<sup>21</sup>. In Europe alone, garlic is marketed as a foodstuff, a herbal supplement, a herbal medicinal product, a food supplement, a health food or as a pharmaceutical preparation; however, it may not be marketed

as a dietary supplement because European Union directive restricts use of that term to vitamins and minerals. In contrast, in the USA garlic is classed as a food or as a dietary supplement only. In Bangladesh garlic is sold as a “phytoprotectant”, as a “functional food” in Nepal, and as a “phytotherapeutic agent” in Brazil<sup>22</sup>. This lack of consistency in terminology contributes to the complications inherent in the regulation of traditional medicines and quantification of their international economic role. Statistics on the sale of specific traditional medicines are understandably difficult to gather in light of the array of classification options.

**Figure:1**<sup>23</sup>



**Figure :2**





**Discussion:** In summary, the following things can be regarded as a lacuna, it is found out that that the overall trend of herbal patent filing has not declined in the face of litigation in the mid-1990s but does flatten out once the TKDL project gained momentum in 2003. It is also clear that starting 2006, the mix of herbal patents shifts towards patents that are a combination of herbal and synthetic formulations. Finally, it is found that f that herbal patent filing in the U.S. is driven by scientists of Indian ethnic origin; most likely by migrant Indian scientists. From the review it is relevant that around the world where traditional IP has been “stolen” by western entities. A relevant example from Mexico relates to the Enola bean that was patented in the U.S. By obtaining a patent and a U.S. Plant Variety Protection Certificate, Colorado based Larry Procter is claimed to have secured “a legal monopoly over yellow beans sold in the

United States”. However the Mexican agricultural community claimed that the patented bean was “a descendant of the traditional Mexican bean from the Andes, the Mayacoba”, that had “better yellow colour and a more consistent shape”. Not only are these Indian traditional herbs also being patented by other countries though the science of Ayurveda has pointed their uses ages before.

**Conclusion:** Ayurveda is the pioneer of medical science. Over the years the knowledge is being subsided due to lack of literature thus leading to improper understanding of the science. In recent years Ayurveda has provided miraculous lead compounds that has shown tremendous therapeutic efficacy with minimum side effects as possible. Thus to preserve, conserve and deliver this science to the world Intellectual Property Right must be maintained until the compounds are validated by experts dealing with it.

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