Intellectual Property Rights: Bane or Boon for Unani Medicine?

Name: Mayuree Sengupta  
Designation: IP Practitioner, Alumnus-IIT Kharagpur  
Email Id: mayuree1sengupta@gmail.com
Abstract

Traditional medicine in India is represented by a rich and diverse heritage, of which the Ayurveda, the Siddha, and last but not the least, the Unani systems of medicine are widely recognized and are more or less standardized. Drugs based on herbal formulations are popular; without resolving the issue of Intellectual Property Rights (IPR) protection. On one hand, certain commercial organizations are aiming to monopolise herbal formulation based drugs vide patents, on the other hand, efforts are being made in the form of documentation (Traditional Knowledge Digital Library: TKDL) of ancient knowledge to uphold the rights of scores of Indians to practice knowledge handed down through generations. Approximately more than 1000 patent applications worldwide could be found based on traditional Unani formulations. In case we fail to provide protection to the medicines and Unani formulations, based on traditional knowledge then it would be difficult to provide and uphold global protection to IP Rights.

In the literature, several authors have analyzed different techno-legal aspects of IPR but not delved into present topic of interest. This paper aims to investigate the pros and cons of IPR vis-à-vis Unani medicine and ascertain whether IPR proves to be a bane or boon for Unani medicine in the long run. Case studies offering different facets of patents and Unani traditional medicine standoff are also delved into.

Keywords: Case-studies, Intellectual Property Rights (IPR), Medicine, Patents, Unani.
INTRODUCTION

World Health Organization (WHO) defines ‘Traditional Medicine’ as “The sum total of all 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 observation handed down from generation to generation, whether verbally or in writing”. This renders it unsuitable for protection under modern framework where everything is based on documentation and is applied to all countries uniformly.¹

The Unani system of medicine is based on well established knowledge & practices, relating to promotion of positive health & prevention of diseases. The Unani system originated in Greece and passed through many countries; each enriching it with their own aptitude and experience. The system was brought to India during the medieval period by Arabs. It has grown out of the fusion of devices, thoughts and experience of countries with ancient cultural heritage, namely, Egypt, Arabia, Iran, China, Syria and India.² The Unani system emphasises on the use of naturally occurring, mostly herbal, medicines and also uses few medicines of animal, marine and mineral origin. This system of medicine was documented in Al Qanoon, a medical Bible, by Sheikh Bu-Ali Sina (Avicena) (980-1037 AD), and in Al-Havi by Razi (850-923 AD) and in many other books written by eminent Unani physicians. However, most of this available documents are in Urdu, Arabic and Persian languages; thus having limited readers who are well versed in these languages. Albeit Unani is a codified medicine system, it lacks well documented evidence of safety, efficacy and quality that characterizes drugs.

Intellectual Property Rights (IPR) refers to the legal rights granted with the aim to protect the creations of the intellect.³ Intellectual Property (IP) is a valuable corporate asset and a strategic business tool. Increasing significance of intangible assets is forcing business organizations to actively manage intellectual property as a key driver for building and sustaining competitive advantage. Drugs based on herbal formulations are popular and enjoy a wide geographical market. Profit driven organisations which develop and market such herbal based drugs are further motivated to patent their formulations and/or product. Patent, which is a form of intellectual property used to protect scientific innovations, entitles an inventor to enjoy monopoly rights for a limited period in lieu of making the invention public. Thus, others are prevented from making, using or selling the patented product or process without consent of the inventor.⁴ The conflicting issues that may arise out of upholding rights related to traditional medicinal knowledge of the communities viz. Unani under the existing patent rules in the light of patenting herbal formulations need to be resolved.

The study is based on secondary research. The methodology adopted includes a detailed study from various sources.⁵ The primary sources of study mainly comprise the documented Unani formulations and multi jurisdictional patent office listed information. Secondary sources

⁴ Section 48, Indian Patents Act, 1970.
⁵ Industry sources remain anonymous due to privacy concerns.
encompass journal literature, legal electronic discussion lists, blogs and other key internet resources and guides.

**UNANI MEDICINE VIS-À-VIS IPR: CONFLICTS & CONCURRENCE**

It has been argued that patenting is an incentive for researchers to develop new remedies for the welfare of mankind. When profit driven commercial organizations aim to develop enhanced products out of naturally available raw materials used for the same purpose through ages by indigenous generations, a conflict of interest of IPR with traditional practices such as Unani medicine system ensues. Often such organizations incur high expenditure in R&D to develop a product. They apply for patent protection so that they can accrue profit out of it. Are we justified in denying that right? At the same time, patent rights sometime tend to supersede and violate the ‘inherent natural rights’ of a human being to healthcare and essential medicines. Should our ethical decisions be governed by the market forces or by humanitarian concerns?

But before clarifying such doubts, it will also be pertinent to note that certain unscrupulous organizations work on herbal formulations mostly derived from well known sources of natural origin and tend to obtain IP rights over it. When they attempt to patent inventions which have no novelty; patent examiners cannot ascertain whether any relevant prior art exists as the documentation is not in their official language of use. This has multi level repercussions.

Firstly, those organizations either by ignorance or driven by greed are aiming to monopolize knowledge that rightfully belongs to its traditional users. In the process, they also attempt to override the basic eligibility criteria pertaining to newness of an invention. Secondly, once a patent is granted, the traditional practitioners are precluded from using it due to monopoly granted to the patent holder.

Patents reward innovation; and providentially examination process of an application is stringent – judging it on the basis of novelty, non-obviousness and industrial applicability. So, knowledge of Unani formulations, documented or oral is adequate to challenge the validity of an application: before or after grant as per law.

Also, traditional knowledge as prior art is recognised and acknowledged worldwide. Any misappropriation of such knowledge is deemed to be biopiracy and one can seek legal remedies against it.

This way, there is a synergistic assimilation of principles. Thus, an impending conflict of Unani Medicine vis-à-vis IPR could be amicably resolved. The following case studies offer different facets of patents and Unani traditional medicine standoff.

---


---
Case Studies

1. *Glycyrrhiza glabra* Case Study

The EPO patent application number EP1859834, titled ‘anti-inflammatory agent’, was filed on 15 March 2005 by Maruzen Pharmaceuticals, a Japanese pharmaceutical company (established 1985). The designated states are Germany, France and Italy i.e. the applicant intended to use his invention in these countries. The applicant claimed that *Glycyrrhiza glabra* is useful for the treatment of inflammation.

However, there exists evidence that the same plant has been used for the treatment of inflammation/swelling for centuries generally in the Indian systems of medicine and particularly in the Unani system of medicine. The prior art shown in Figure 1 is from a famous Unani book,

![Figure 1: Prior art mentioning *Glycyrrhiza glabra*](image)

written in Urdu, a century ago. This is one of the reference books of Unani medicine in the academic syllabus. The detailed bibliography of the citation is as follows: Khazain ul advia by Hakim Mohd N. G. Khan; vol. VII; published by CCRUM, Dept of AYUSH, Ministry of Health and Family Welfare, Govt of India. 2010, p. 229. This prior art shows that Mulahti *Glycyrrhiza glabra* is useful for the treatment of inflammation.\(^8\)

Legal status analysis by author of EP1859834 reveals that dispatch of examination report was done on 23.11.2012 & examination is in progress. The patent applicant had replied to a communication from the examining division on 26.02.2014; the particulars of which are awaited.\(^9\) EPO has the option for third parties to provide information on Facts & evidence, Novelty, Inventive step and other factors (e.g. clarity) regarding any patent application filed. The

---


onus lies on Unani practitioners, TKDL\textsuperscript{10} and AYUSH\textsuperscript{11} to submit their observations so that such prospective patents get rejected, lacking novelty and other patentability criteria.

If such patent applications are not opposed, not only will the MNCs get a monopoly over the drug for 20 years, but also eat into the market share of Unani medicines in economically viable European and other markets. Also, once a patent is granted, the product naturally acquires a reputation and can prevent similar formulations from capturing the market. To facilitate greater foreign revenue, it is necessary that the interested stakeholders come forth and keep a tab on such applications worldwide.

2. Narcissus tazetta Case Study

Nargis (\textit{Narcissus tazetta}) is a famous plant having various medicinal properties as documented in ancient Unani classical literature. It is used as solvent (mohallil), absorbent/absorbefacient (jaazib) and jaali (detergent), and also for the treatment of ‘balkhora’ (\textit{Alopecia areata}) as mentioned in \textit{Khazainul Adviyah} by Ghani. Moreover, it is useful for the treatment of ‘Kalaf’ (freckles), and bahaq (Ptyiasis) as mentioned in \textit{Al-Qaanoon-fil-Tibb} (AD 981–1037).\textsuperscript{12}

A patent application (patent no. 04005448.8) with publication number EP1718143\textsuperscript{13}, published on 8 September 2004 is as follows: ‘Agents for sequestering serum ageing factors and uses therefore’. The applicant of this application is Nu Skin International Inc [US]. The patent claims that the Narcissus product can be used for preventing damage to the skin, treating the damaged skin, preventing a complication of the primary disorder and preventing the secondary disorders, when in all the above cases the complication results from oxidative damage resulting from the generation of reactive oxygen species by arNOX.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure2.png}
\caption{Prior art mentioning \textit{Narcissus tazetta}}
\end{figure}

\textsuperscript{10} Traditional Knowledge Digital Library.
\textsuperscript{11} Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy.
Figure 2 shows two prior arts of Unani classical literature that can be used to oppose the novelty and inventiveness of the claims of the patent application in which N. tazetta has been used for the prevention and treatment of damaged skin. One of them, taken from Al-Qaanoon-fil-Tibb (Canon of Medicine) refers to a description of N. tazetta as a single ingredient used in the treatment of alopecia through local application. Another art taken from Al-Jaame’-li-Mufradaat-al-Adviawal- Aghzia refers to a formulation containing N. tazetta as a single ingredient used in the treatment of alopecia through local application.

The alleged invention claims the use of N. tazetta for the prevention and treatment of damaged skin resulting from conditions like acne vulgaris, atopic dermatitis, alopecia, vitiligo, pruritus, eczema, etc. However, the fact that N. tazetta has been used singly and in combination with other constituents for treating alopecia, pruritus and vitiligo through local application as is seen in the prior art is a valid ground for anticipation.

Legal status review of EP1718143 reveals that the application has been withdrawn. So, no economic loss is suffered by Unani practitioners industry in this case.

3. Artemisia (Wormwood) Case Study

Many species of herbs extracted from Kashmir have gained worldwide fame due to their medicinal/aromatic values and different species of Artemisia (Wormwood) is an important one amongst the many. It is used in preparing different Unani formulations. A search by the author for patents based on this plant revealed the following findings:

   a) Method for isolation of artemisinin from Artemisia annua (Patent no. 4,952,603)
      Artemisinin is an antimalarial agent. CSIR is the assignee of this invention which was filed in 1988 and granted in 1990.
   b) Process for isolating artemisinin from Artemisia annua (Patent no. 6,685,972)
      CSIR is the assignee of this invention which granted in 2004.
   c) High artemisinin yielding artemisia plant named ‘CIM-arogy’(Patent no. 7375260)
      CSIR is the assignee of this invention which was filed in 2006 and granted in 2008.
   d) Method for maximization of artemisinin production by the plant Artemisia annua
      (Patent no. 6,393,763)
      CSIR is the assignee of this invention which was filed in 2000 and granted in 2002.
   e) Association between ferroquine and an artemisinine derivative for treating malaria
      (Appl No. : 11/874,377)
      Sanofi Aventis is the assignee of this invention which was filed in 2007.
   f) New series of Artemisinin derivatives and process for preparation thereof
      (Appl No. : 13/574,440)
      CSIR is the assignee of this invention which was filed claiming priority of the application titled A New Series Of Artemisinin Derivatives With Potential Anticancer Activities [127/DEL/2010] filed on 2010.
   g) Method of preparing pharmaceutical artemisia extract and apparatus for electrical moxibustion using the extract (Patent no. 6,251,380)
Kijang Medical Co. is the assignee of this invention which was filed in 2000 and granted in 2001.

h) Method for treating type 2 diabetes with an extract of Artemisia
(Patent no. 6,893,627)
Rutgers, The State University of New Jersey is the assignee of this invention which was filed in 2002 and granted in 2005.

New plant varieties of Artemisia have also been granted protection:

i) US20040237162: Artemisia plant named "Golden Phoenix" (Patent no. USPP16046)
The application for this invention was filed in 2003 and patent issued in 2005.

j) Artemisia plant named ‘Dueparethio’ (Patent no. US PP23017)
Capital Green Investments Ltd. is the assignee of this patent issued in 2012.

Although the abovementioned list is not exhaustive, yet it can logically be inferred that there is great economic potential of the curative properties of Artemisia. Myriad applicants of the patent applications included government organisations like CSIR, universities like The State University of New Jersey, companies like Sanofi Aventis as also individual inventors. Moreover, it is also essential to note that since Artemisia extracts are known to have anti malarial to anti cancer properties, therefore Unani practitioners could benefit by utilizing the plant more meticulously.

4. Adhatoda vasica Case Study

Vasa (Adhatoda vasica) is a well known drug in Unani system of medicine. It is recommended for various ailments like bronchitis, asthma, fever, jaundice and consumption. Its therapeutic properties are attributed to vasicine and the essential oil.

A search of related patents by author revealed:

a) Japanese patent JP7157420 was filed by Mikimoto Pharmaceutical Co. Ltd in 1993. The title of the patent is 'Cosmetic'. The aim of the patent is to obtain a cosmetic having improved whitening, antioxidation and hyaluronidase inhibiting activities and an improved moisture holding property by cholesteric liquid crystals.

b) Japanese patent JP7118135 was filed by Nanba Tsuneo and Mikimoto Pharmaceut Co. Ltd jointly. The title of the patent is coincidentally 'Cosmetic'. The purpose of the patent is to obtain a cosmetic containing solvent extracts of Adhatoda vasica used for food for many years being safe to human body. It also helps in whitening action and inhibiting the activity of hyaluronidase.

c) Chinese patent (Appl No. : 200810160437) titled ‘Adhatoda vasica skin-bright astringent’ was published in 2010 and relates to anti-inflammatory effect and the effects of moisturizing, antioxidation and hyaluronidase inhibition in makeup.


The case studies would disclose that barring CSIR attempts, India lags behind other developed and developing nations as far as patenting novel natural resource derived products are concerned. Also, Indians ought to be more keen in keeping track of such patent applications and tactfully opposing traditional medicine based patent applications across jurisdictions.

CONCLUSION

The pertinent question is whether IPR will prove to be a bane or boon for Unani medicine in the long run. Protection of IP Rights fosters economic growth and attracts foreign investment. We must at the same time acknowledge that in countries like India there are many great treasures of knowledge and wisdom created by people, who may not have had formal classroom education but because of robust common sense and in-depth study of nature and experience have accumulated huge treasure of knowledge.\[^{16}\]

Traditional knowledge in all fields particularly in the field of medicine and Unani formulations must be properly preserved and protected. If IPR regime is robustly implemented in India, not only will inventors worldwide be interested in protecting their IPR here but also spurious patent applications and surreptitious attempts to get Unani formulations registered as trademarks will gradually cease.

TKDL work on Unani Medicine is in progress. The transcription of target 77000 formulations which are in Urdu, Arabic and Persian languages from 42 Unani books is being carried out. Moreover, AYUSH is also keen to develop products having IPR potential to boost exports. The stakeholders and TKDL, AYUSH should actively promote India’s traditional knowledge base and aid to protect IPR in foreign jurisdictions.

It can be justifiably concluded that if managed properly, IPR can prove to be a boon for Unani medicine in the long run.