

## Review Article

# Healing beyond borders: intellectual property, traditional knowledge, and the future of Unani medicine

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## ABSTRACT

There are unique issues and opportunities related to intellectual property in the development of modern Unani medicine. With increasing global interest in traditional and herbal medicines, Unani pharmaceutical companies face the challenge of continuously improving their products while staying true to traditional knowledge. Therefore, patent protection and compulsory licensing are essential in this transition process, balancing invention rights and public health concerns related to Unani treatments. Patents encourage innovation by providing exclusive rights for specific solutions and techniques, often attracting venture capital for development. However, these rights can also limit access, especially in poor regions where traditional cures are most needed. Compulsory licensing offers a viable alternative, allowing governments or authorized bodies to produce patented medicines without the patent holder's consent in certain situations, such as in the public interest. In Unani medicine, compulsory licensing may be particularly useful for regulating patent-holding companies and ensuring they respond to societal needs by providing necessary treatments. This paper explores how patents and compulsory licensing influence Unani pharmaceuticals, focusing on how policy makers shape and enforce intellectual property rules to manage commercialization, access, and international market growth. It is crucial to balance the use of traditional Unani medicine to make it a practical, culturally sensitive, and affordable healthcare option for the global community.

**Keywords:** Intellectual property, Unani medicine, Patents, Compulsory licensing, Traditional knowledge

## INTRODUCTION

Unani system of medicine is also known as Yūnānī Nizām-i Tibb or Tibb, and as it is clear from its name, traces its origin directly to ancient Greece (Yūnān). As Medicine was borrowed from Egypt by the Greeks, therefore, we need to go back to Egypt and Mesopotamia as sister civilizations. It was taken over by the Arabs, who in turn developed it and added on to it immensely.<sup>1</sup>

The Unani system of medicine is a discipline based on the humoral theory of Hippocrates. The human temperament often refers to the predominant humors: sanguine (Damawé), phlegmatic (Balghamé), choleric (Safrāwé), and melancholic (Sawdāwé), which may be associated

with diet, pharmacological substances, environmental factors, and other things. Unani doctors initiate the administration of these medications according to the patient's type, the causative humour, the functionality of the affected organ, and the severity of the ailment. These are classified according to temperament (Mizāj) and are designated as first, second, third, and fourth degree depending on intensity.

Modernization has enhanced its importance today, and it is now an important part of the current world of medical practice. Unani medicine is shifting gradually with the steady exploration, the advancement in technology, and the acceptance of the Unani system in academic curricula all over the world. Such evolution ensures that the practice

is effective as a complementary medicine with Allopathic medicine, as it serves the customer needs of contemporary society that embraces diversified medicine that complements the traditional one.

The multifaceted impact that patents and compulsory licensing exert on the Unani pharmaceutical industry is the focus of this paper, with specific reference to the ways the regulation of intellectual property rights shapes the industry's commercialization initiatives, stakeholder access to, and its export overseas. The exploration reveals how such an IP architecture can either promote or obstruct the dawning of the Unani system, as it needs to overcome exercises of modernity and incorporation. To enhance the performance and practice of Unani medicine, there is a need to realize this middle ground between patents and compulsory licensing. Such a balanced strategy guarantees the continued relevance of Unani as a health care system, which is still of cultural significance, as well as ensures that it is a viable commodity in the global market. The outcomes of this study shall be used to guide policymakers, industry stakeholders, and researchers in their decision-making and policymaking to enhance the sustainable development of the Unani pharmaceutical industry.

## THE MODERNIZATION OF UNANI MEDICINE

### *Modernization in the Unani context*

India is one of the few countries that have accepted the concept of multiple valid traditional health systems, such as Ayurveda, Unani, Siddha, Yoga, Naturopathy, Homeopathy, and Allopathic systems. Dr. Hakim Ajmal Khan (1868-1927 AD), an eminent scholar and a much-respected doctor who introduced a vast change in the Unani System of Medicine involving teaching, research, and practice reforms. His dream was realized, similar to the establishment of the Ayurveda and Unani Tibbia College in Karol Bagh, New Delhi.<sup>1</sup>

To enhance people's ability for the traditional system of medicine after the Alma-Ata declaration of 1978 on "health for all" and to mobilize traditional medicine and its practitioners for the delivery of primary health care, policies and strategic interventions were developed. World Health Organization (WHO) expanded support for these interventions in member countries by producing technical bulletins and guidelines.

To ensure the quality standardization of Unani drugs, quality control measures have been initiated by the Government of India and brought into operation good manufacturing practices (GMP) under schedule 'T' of the Drugs and Cosmetics Act, 1940. The Act governs the production as well as the sale of Unani drugs. This also serves the purpose of confirming the authenticity of the raw materials employed in the production of drugs to be genuine in regard to standards laid down.<sup>1</sup>

For the most part, the Drug Standardization Research Program attempts to enhance the pharmacopeial standards of Unani medicine, which forms part of the National Formulary of Unani Medicine (NFUM). Furthermore, the Essential Drugs were well identified and properly included in the list that requires a monograph in the essential UPI production areas, while the production and the related SOPs of the essential drugs were developed and standardized during the operationalization of the study. They were set out in the pharmacopeial standard books, common with pharmacopeial standards.<sup>2</sup>

### *Key modernization challenges*

The present challenge for Unani scholars is to substantiate some of the claims on the line, such as the method of identification of primitive drugs, their authentication methods, clinical efficacy, and their method of formulation, and the possible expiry dates of compounds through scientific temper. A validation of these claims is the challenge for all Unani pharmaceuticals. This is also the case with its global promotion.

Another issue is the standardization of crude pharmaceuticals and compound formulations, as explained by Unani specialists, which is based on experience. The records with regard to them may only appear as declarations of several officials. As they are appearing to be quite accurate, nonetheless, they cannot be viewed on the same par as the scientific assertion. These statements have to be proved, and the medications need to be characterized on these finer scientific standards. Another problem of the Unani system is that assessment of dosage form based on a modern approach is highly sensitive, so that it becomes acceptable and pleasant to all.<sup>3</sup> Compliance with pharmacopeial standards for Unani medicines, as prescribed in the Unani Pharmacopoeia of India, can improve the quality, safety, and credibility of Unani medicine.<sup>4</sup>

### *Opportunities for integration with modern healthcare*

The Unani system of medicine is more realistic about disease because it takes into account several factors, which are involved in the development of most diseases, and focuses on the management of lifestyle, both for the maintenance of health, prevention, as well as treatment of NCDs. Whereas conventional medicine is mostly limited to the curative aspect, there is much possibility in disease prevention in the Unani system of medicine.<sup>5</sup>

The season or nature of air, food, and drink, and those conditions within the body of the patient, whether it is motion or rest, wakefulness or sleep, and voiding and holding of urine, fall under the Unani therapy method. It has linked all of these elements with people by identifying their Mizaj, or temperament. Thus, the Unani System of Medicine has a valid role in today's world relating to any disease having non-communicable origin, such as depression, diabetes, and hypertension diseases which

have a great burden in the current health care system in view of its potential to extend the health promotion and disease prevention throughout.<sup>6</sup>

## PATENTS IN UNANI MEDICINE

A patent is a legal instrument issued whereby an invention created by an inventor is protected by the government so that only the inventor in question can produce, use, and sell the invention throughout a stipulated time. A patent legally gives its holder the right to hold a monopoly to control the market and reap handsome monetary benefits, which is justified against disclosure of innovation by the patentee to the whole population. After the conclusion of this defined time, the invention may be utilized in general without fetters. A patent has geographical aspects and is enforced on the basis of its registration in each nation.<sup>7</sup> Joint management of intellectual property right (IPR), patents, and traditional knowledge has become significant for its producers and the body of intellectual thought of the world at large.<sup>8</sup>

### *Benefits of patents for Unani Medicine*

#### *Incentives for R&D and investment*

The ability to introduce novelty is evidenced by increased investments in Indian herbal research activities and manufacturing facilities situated beyond the Indian region. As per Article 27 of Trade-Related Aspects of Intellectual Property Rights (TRIPS), patents are to be granted for innovations in any technological field and for any new process or product that is not created previously (emphasis added), and that is not only novel or aesthetic or involves an element of creativity but is also an industrial application. The value of a nation's economic status depends on its efficiency in the utilization of intellectual property. As a matter of fact, companies such as Hindustan Unilever, Avesthagen, Ranbaxy, Himalaya, Sahajanand Biotech, Panacea Biotech, Natural Remedies, and Indus Biotech submitted a larger number of PCT applications than the Indian companies.<sup>9</sup>

### *Protecting traditional knowledge (TK)*

Bio piracy is a major issue in traditional health care advertising. As a result, the credibility of traditional information is important for our prospects.<sup>10</sup> Many of the literature documents on Unani medicine are available in Arabic, Persian and Urdu, and other languages. Since most literary resources are easily accessible, many of them are prone to being infringed among literary resources. Bio-prospecting is being carried out with the Unani medical system. Since it is assumed that it is free for the public and that communities have no claim over it, then it is abused.<sup>11</sup>

The elaboration of the Traditional Knowledge Digital Library (TKDL) project was launched in 2001. To prevent the issuance of wrong patents, it provides knowledge about the conventional information of the country in languages

and modes understandable to examiners at International Patent Offices (IPOs). The TKDL has information on 2, 92,662 medicinal formulations from IMSM literature till April 2016, and out of these, 1, 75,150 belong to the Unani system of medicine.<sup>1</sup>

### *Challenges in patenting Unani products*

The call for the professionalization of Unani by the Western model has been made by Unani practitioners. There was consensus that the culture of Unani needed to be spread, or in the words of its proponents, vernacularization of Unani had to be made. As they saw it, this was the only way to compete with British-sponsored materia medica and pharmacopoeia in the vernaculars.<sup>12</sup>

Most of the complications associated with the incorporation of herbal medicines have been found to occur most of the time due to some governments categorizing those products as foods or merely as supplements. Virtually every herbal preparation can be marketed with little or no demonstration of quality, potency, or safety on the market. Consequently, the quality testing and manufacturing standards are relatively low or less stringent, especially for herbal medical products, and even the traditional healers, in some instances, are not even certified. Consequently, the safety of traditional as well as herbal remedies emerged as a paramount factor in the appraisal of the national medical professionals as well as the society at large.

Of particular interest is that the elements of quality and purity used in the production of botanical products include core (genetic) constituents as well as other constituents, such as good agricultural and collection practices (GACP), which consists of crop selection, crop growing, and collection. Since it is said to bear all of these problems at once, there is virtually no way the proper quality control of raw materials can be practiced. WHO recommended for formation of institutions for I and C measures, which provide good manufacturing practice (GMP) for herbal products, licensing, and labeling for production, trade, and promotion of such products in the country. Other problems: unethical training on herbal drugs, scarcity of qualified herbal practitioners, disclosure of fluctuating and ambiguous data, inadequate funding, lack of enthusiasm for motivating marketing and labeling, lack of knowledge about herbal medications, and international advertising of such items. One concern is that there were insufficient conservation of ecosystems and an absence of safeguards for conventional medicinal plants.<sup>13</sup>

## COMPULSORY LICENSING UNDER PATENT LAW AND ITS APPLICATION TO UNANI MEDICINE

Theoretically, the term compulsory licensing means, "When the government permits other interested parties or itself to make use of a patented invention for manufacture and sale without the consent of the patent holder. It is a

statutorily created license that allows certain people to pay a royalty and use an invention without the patentee's permission". Rights arising out of such compulsory licenses are presumably considered as rights granted by the patentee itself. Such interference with the intellectual property rights of the patentee, or we can say the conflict of his interest, is justified when it is done in a statutory way that too, with the intention of social welfare.<sup>14</sup>

The Organization of Pharmaceutical Producers of India estimates that India is ranked third in pharmaceutical industry output volume. The Indian Patent Act has elaborate provisions relating to compulsory license to cater to the needs of individuals in the case of patented goods, so that no monopoly in the patent rights is exercised improperly. Section 84 of the Indian Patents Act 1970 states that after three years, a compulsory license may be issued for the patents.<sup>15</sup>

The UN recommends that countries develop laws enabling rapid and nondiscriminatory CL issuance in order for legitimate public health needs, particularly those related to the availability of essential medicines. The Doha Declaration further supports the discretion of national governments in determining when to issue a compulsory license, which has also heightened the emphasis on public health over IP rights.

Notwithstanding its benefits, CL also opened itself to several challenges and controversies, more so with the emergence of what is called the grey market. Grey markets are formed when, out of a designated market for a product, the products land in other markets where they are sold at lower prices than their listing price, leading to a loss of revenue and possible infringement of IP.

A number of these issues could be avoided by turning grey dealers into official sales partners with clearly defined channels in place to ensure economic benefits for everybody. This would, on one hand, allow controlled distribution while ensuring the protection of quality and safety for the consumer of such products. Labelling solutions are also proposed, special watermarks or holograms on CL-produced products, which can prevent entry by unlicensed holders into the market.

On the other hand, some patent owners maintain that CL cannot stimulate innovation. Inventors and companies heavily invest in R&D, believing that they will get returns by financing constant innovation. Patent owners feel that CL affects their ability to commercialize their inventions and may develop cold feet against continuing research. On the other hand, proponents of CL counter that licenses are issued only in cases of emergency or unmet need, and therefore, the mechanism does not arbitrarily undermine patents. At the time of applying for CL, an applicant has to first apply for a license voluntarily from the patent owner and apply for CL only when a refusal is received from the patentee.

CL also presents some of the challenges related to the determination of "adequate remuneration." TRIPS prescribes reasonable compensation without laying down its method of computation and hence leaves it to the countries to strike a balance between the interests of a patent holder and other parties. The nature of the invention and the patentee's cost are some of the limiting factors under the Indian Patents Act, on the Controller of Patents, while granting compensation for CL.

Compulsory licensing remains a complex but important tool for striking a balance between public health needs and IP protection. As such, the CL provisions within the patent regime for India are steps in meeting the constitutional mandate to improve public health while creating an environment that respects the rights of patent holders. As CLs are picking up on the international picture, it has become a 'credible threat' to the patent holders. It may entail dismal consequences as it will make the exercise a highly commercialized affair, as countries may resort to it only to procure drugs at a lower rate.<sup>16</sup>

## THE FUTURE OF UNANI MEDICINE IN A GLOBALIZED MARKET

Even in the present day, some Asian countries such as China, India, Japan, and Pakistan continue to embrace traditional medicine. The present global herbal and ayurvedic medicine market is US\$ \$ 103 billion, with the EU occupying 40%, Japan 20%, and the USA about 10%. India is called the "Botanical Garden of the World". Lucknow grows medicinal plants of 100 crore US dollars annually, and the European Union uses 3000 kg of Glycyrrhiza each year, for which 400 tons of plant roots are needed.

To determine the efficiency of several Indian plants and herbs, the center was established through a Memorandum of Understanding by the Department of AYUSH, Government of India, and the Department of Pharmacognosy, in the University of Mississippi Foundation. More than 13,000 plants have been investigated in the last five years.

The Global Unani Medicine and Research Foundation (GUMRF) was formed under the law of the United States of America. The foundation has five overseas offices located in Asia, Europe, the Middle East, Africa, and Australia, besides the head office in Chicago. The main objective of the GUMRF is to provide the Unani scientists, practitioners, and well-wishers of the world a chance to finance Unani research and healthcare projects.

There is no doubt that the Unani system of medicine has been accepted worldwide because it is affordable, easily accessible, and free from severe side effects.<sup>17</sup> The Alma-Ata Declaration of 1978, for the first time, envisaged that traditional medicine could be used to deliver primary health care. There should be the promotion of policies of innovation in the area of TM under the WHO Global



strategy and plan of action on public health innovation and IP (2008). The authors call for the improvement of the understanding of the mechanism of action of TM as well as its pharmacokinetics, as described in paragraph 3.4 on page 31 of the report.<sup>18</sup>

The global AYUSH economy was 3 billion USD of which India has accounts for 400 million USD, which means great potential to capture the world market as much knowledge is accumulated and used in India from centuries, the TKDL is database containing knowledge of the drugs and herbs used in India since Vedic period, can be a treasure if managed properly.

In Unani research, eight patents have been filed out of which seven were filed by the Central Council for Research in Unani Medicine, and a single patent was filed by Fareed Nadia Siddiqui. The following illnesses are covered by the patents that have been filed; haepatitis, asthma, and polycystic ovarian disease.<sup>19</sup>

## SUCCESS IN COMMERCIALIZING UNANI FORMULATIONS

The success of Unani formulations in the commercial sphere can be seen through the rise of companies like Hamdard Laboratories and other Ayurvedic and Unani companies, which have established Unani medicine as a viable commercial sector. Hamdard, one of the pioneers of Unani medicine in India, oversaw the successful process and commercialization of such formulations as Roghan Badam Shirin (almond oil) and Joshina (herbal cough remedy), among others, into household names. By focusing on quality, research, and the effectiveness of traditional products. Hindustan gained consumer trust and expanded from its home market in India to several Middle Eastern and Asian countries.

Additionally, investment by the Ministry of AYUSH in India and recognition of the certification processes have intensified the reliability and business components of Unani, which endorse an environment favorable to business success. Improved standardization of products and modern packing also contributed to establishing the Unani formulations, side by side positions among other conventional pharmaceutical products in both Urban as well as international markets. Today's users turn to Unani products to lose weight, consuming Safoof Mohazzil, and to promote liver health, having Habbe Jalinoos. Every single one of these factors interests the modern consumer and shows the versatility and effectiveness of Unani medicine in the system of health and wellness.

## CONCLUSION

Unani system of medicine, which originated from the ancient Greeks' approach, supports the use of a holistic style of dealing with the disorders of the human body and the subsequent treatments to bring balance in the bipolar humors and to the temperaments of the body. Although the

Unani system of medicine has its roots in the past, the present-day concerted efforts at modernizing it face several challenges, primarily in regard to quality and safety, and the requirement of scientific evidence. Issues like biopiracy also pose some risk because sometimes outside parties will patent traditional medicines with a little tweak. To protect such knowledge, initiatives such as the TKDL of India try to index traditional formulations so that they cannot be patented.

These are legal policies that need to be embraced if there is to be development of the Unani medicine science and more investment in it. Patents preserve the exclusive control of the inventor and thus offer encouragement to fund R&D for new therapies using the Unani system of medicine. However, the exclusivity of patents may deny the targeted populations such treatments as those in the Following communities. Compulsory licensing can therefore be seen as offering such a right by allowing a third party to produce a patented medicine to fulfil social purposes and thus offer the opportunity to get accustomed to it.

In order to implement patents and compulsory licenses for modernizing Unani medicine, the policymakers should concentrate on the following seven tactics. Firstly, their officials should explain what forms of Unani innovations are protectable to encourage the inventive activity or the generation of new knowledge in this field, which can be referred to as R&D. It is important that traditional knowledge should be protected, and efforts should be made to strengthen the resources, such as the Traditional Knowledge Digital Library or TKDL to safeguard Unani formulations from biopiracy. Government support, as well as the financial and scientific potential of academic institutions and industry partners, could be promoted to make PPPs a powerful tool for driving innovation. It is thus imperative that a strong public compulsory licensing regime is developed to address the public health need for Unani medicines when the prices caused by patent rights become prohibitively expensive. Enhancing the GMP of Unani products is as follows: to bring Unani products up to par with modern health concerns, the problems associated with uncontrolled herbal products would be solved. Also, the development of a much-desired regulatory framework that will conform to WHO recommendations will provide the much-needed direction to quality control, clinical trials, and licensing for Unani medicine. Last but not least, policy makers should strive to increase visibility of Unani patents across the globe, especially in countries where demand for traditional medicines is high, so as to maximize possible business opportunities of Unani ideas.

In an envisaged synergy, these measures would help in developing Unani medicine sustainably and in context with the modern world's needs and demand.

However, the following directions need more consideration for the development of Unani medicine:

ethical and environmental issues include community consent to use traditional knowledge and the use of sustainable harvesting techniques. Such an approach could potentially revolutionize Unani medicine practice through the infusion of innovation with issues related to do with accessibility as well as ethical issues. For Unani medicine to become a part of the solution to global health care needs, it is important to acknowledge, reinvent, patent, and standardize this knowledge base on the lines of the current global paradigm.\_

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