

# Protecting Medical & Pharmaceutical Inventions in the GCC Countries

by Ahmad Saleh - ah.saleh@tamimi.com - Dubai International Financial Centre  
Houda Meliani - h.meliani@tamimi.com -

November 2015

Pharmaceutical and other healthcare entities invest tremendous amounts of money each year researching and developing new medical and pharmaceutical products.

Those that make this investment do so in the hope of creating new innovative products that can be commercially exploited at the exclusivity of their competitors to secure a fair return on their investment. To ensure they have the sole right to exploit the developed innovative products, they need to be confident that these can ultimately benefit from patent protection in countries where they are to commercialize them.

This article addresses some of the common questions we receive from clients in relation to the protecting medical and pharmaceutical inventions in GCC countries (i.e. the UAE, Bahrain, Saudi Arabia, Oman, Qatar and Kuwait).

## **How can Patent Protection be Obtained in the GCC?**

There are two routes for obtaining patent protection in the GCC, the national route and the regional route. Patent protection can be obtained through the national route by filing and prosecuting national Patent Applications. If protection is desired in all the GCC countries, separate national applications are to be filed at the respective Patent Office of each GCC country which has its own national Patent Office and Patent law. National patent applications are subject to examination under the national patent laws.

Alternatively, patent protection can also be sought by taking the regional route and by filing and prosecuting a GCC Patent application at the GCC Patent Office. A GCC Patent application is examined centrally by the GCC Patent Office under the GCC Patent Law and once granted, protection would extend to all the GCC countries (subject to certain uncertainties for the UAE). A GCC Patent is also the only available route for obtaining patent protection in Kuwait at present since the Kuwaiti Patent Office has not yet started examining Patent Applications.

A regional GCC Patent can also coexist with other nationally granted patents.

The availability and suitability of each route would depend on the facts of each case.

## **Are Medical Treatment Methods Patentable in the GCC?**

Unlike the US and Australia where methods of medical treatment are patentable, in the GCC region (except Oman) methods of surgical or therapeutic treatment on humans or animals are not regarded as inventions and therefore cannot be patented.

Most GCC patent laws contain specific provisions excluding surgical, therapeutic and diagnosis methods from the scope of patentable subject matter, including Bahrain , Qatar , Saudi Arabia , UAE as well as at the regional level – the GCC Patent Office.

Oman is a notable exception where diagnostic, therapeutic and surgical methods consist of

patentable subject matter, although subject to restricted enforcement against medical practitioners and healthcare entities.

In Kuwait, the Kuwaiti Patent Law is silent in respect of the patentability of medical treatment methods, and as the Kuwaiti patent office has not yet started the process of examining patent applications, it is difficult to confirm the position of the Kuwaiti patent office in this respect. However, since pharmaceutical products are excluded from patentability in this country, it is believed that it is likely that medical treatment methods will also be regarded as non-patentable subject matter.

### **How are Pharmaceutical Products Protected?**

Pharmaceutical products are protected through the protection of novel chemical compounds, pharmaceutical compositions, active agents and other medical substances as well as through the protection of novel and inventive processes used for obtaining medical products. Pharmaceutical products can also be protected by any new crystalline forms (polymorphs) of the active ingredient having desirable physical properties such as improved stability.

### **Are Medical Products Patentable?**

Products used in medical treatments are considered patentable subject matter in the GCC, with a notable exception of Kuwait for pharmaceutical products, and can be granted a patent as long as they are novel, inventive and useful.

Examples of patentable products used in medical treatment methods are medical substances, chemical compositions, medical devices and surgical tools.

The GCC Patent Office and Saudi Arabia have specific provisions for the patentability of products used in medical methods. For the other countries, the patentability of these products is provided under the general provisions of the law such as those defining inventions and patentable subject matter.

Kuwait is a notable exception where “chemical discoveries connected with food-stuffs, or medicinal drugs, or pharmaceutical compositions are not regarded as inventions unless such products are produced by special chemical methods or processes, in which case the patent shall not be in respect of the products per se, but of the process of manufacture”.

### **What are Second Medical Use Inventions?**

Second medical use inventions refer essentially to medical discoveries related to new uses of known chemical/medical substances, such as use of a known medicament for the treatment of a further disease not originally contemplated by the medicament, use of a new dosage regime for administering a drug leading to a new therapeutic effect, and use of a medicament for the treatment of a new group of patients not within the original contemplation of the medicament.

For example, aspirin, originally used as antipyretic and analgesic was later discovered to have new therapeutic uses and it was in consequence adapted to be used as an anti-coagulant and anti-stroke medication. Uses of aspirin as an anti-coagulant and anti-stroke medication are considered respectively as a second and further medical use not originally considered at the time of conceiving aspirin. The US patent covering the chemical compound of aspirin expired in 1917 and the clinical trials and studies leading to the discovery of the second and further medical uses were made between 1960 and 1980. Another notable example is when Pfizer found that sildenafil citrate, known previously for treating heart and vascular diseases, was also useful for treating erectile dysfunction. This product, marketed for the new use as Viagra, has been extremely successful in securing to the patent owner annual sales of billions of dollars.

## **Why is Patent Protection Important for Second Medical Use Inventions?**

When patent protection of the medical substance (such as a chemical compound) is available, this protection would extend to cover use of the compound for any purpose. Protection of a second/further medical use of a known compound becomes particularly important when patent protection of the known compound has expired or never existed.

Without a legal regime for the protection of second and further medical uses of known substances, generic pharmaceutical companies are free to manufacture and commercialise the known compound for any purpose and innovators can lose incentives for conducting further research, clinical trials and studies investigating new uses of known substances. This would hinder the advancement of science and the public benefit.

On the other hand, the availability of patent protection for second medical uses results in granting a monopoly to innovators for the commercial exploitation of the medicaments for the new discovered therapeutic uses and thus increases the cost of these pharmaceutical products on the public and governments which fund these products. This is however seen by the originator companies as being a normal consequence for compensating them for the investment made in terms of Research & Development which can be time consuming and expensive. Countries have therefore adopted different positions on the appropriate level of protection which should be granted for second medical use inventions and uncertainty remains in certain countries as to the availability and scope of such a protection.

## **Are second Medical Use Inventions Patentable in the GCC?**

For some GCC countries, the position is clear with respect to the patentability of second medical use inventions. However for some others, there has been some uncertainty as to the availability of such a protection in the absence of specific legal provision, court precedence and examination guidelines in this respect.

In the United Arab Emirates and Bahrain, the position is crystal clear as patent protection of second medical use inventions is guaranteed under their respective patent laws.

In Oman, second medical use inventions are also believed to be patentable subject matter as this country allows the patentability of medical treatment methods as discussed above.

In Kuwait, pharmaceutical products are not allowed patent protection, and therefore it is believed that it is likely that medical treatment methods and second medical use inventions will also be regarded as non-patentable subject matter. The position of the Kuwaiti patent office cannot yet be confirmed until it starts examining patent applications.

In Saudi Arabia and at the GCC Patent Office, the patent law excludes the patentability of surgical, therapeutic or diagnosis treatment methods "with the exception of products used in any of these methods". Though there is no legal precedence on the interpretation of this exception to the best of our knowledge, in our experience the Saudi Patent Office and the GCC Patent Office are increasingly granting patents for second medical use inventions.

## **What are the generally acceptable types of claims available for the protection of second medical use inventions in the GCC?**

Despite the fact that some examiners continue to raise objections against the patentability of second medical use claims, 'Swiss-typ'e claims covering such inventions have increasingly been found acceptable in the last two years by both the Saudi Patent Office and the GCC Patent Office. Product format claims as adopted by EPO following the G2/08 decision have also been found to be acceptable in some granted patents. Examples of second medical use claims found to be

acceptable:

- “Use of a compound (or a composition) X in the manufacture/preparation of a medicament for treating disease Y”; (the Swiss-type format)
- “A compound X for use in the treatment of disease Y”. (the product format adopted by EPO following the G2/08 Decision)

These claim formats are typically used when inventions are related to the use of a known substance for the treatment of a new therapeutic indication. Pharmaceutical companies can take great benefit from the patentability of the second medical use claim, especially when the product is already known and is no longer protected as such. This fact encourages pharmaceutical companies to continue investigating new therapeutic applications of known drugs to cover existing therapeutic needs. We encourage pharmaceutical companies to use Swiss-type claims covering second and further medical use while filing applications at the Saudi and GCC Patent Offices.

### **What are the Typical Objections Raised Against Second Medical use Claims in the GCC?**

When objections are raised by the Saudi/GCC Patent Office with respect to the patentability of second medical use claims, in most cases they are rejected as being related to medical treatment methods. In some occasions, lack of novelty and/or inventiveness is also raised against the patentability of these.

### **How can Infringement of Second Medical use Related Patents be Determined?**

When the medical substance and first medical use of such substance is already in the public domain (either because patent protection has expired or never existed), it will not be possible to stop generic companies from exploiting the medical substance unless it is used for the treatment of the second medical use covered by the patent. In the GCC, drugs must be approved and registered at the competent regulatory bodies before entering the market. One way of determining whether the medical substance is exploited for a patented use would be to investigate whether the pharmaceutical product has been approved and registered by the competent regulatory body for such a purpose. When the medicament has not been approved for the patented use and the medicament's leaflet information does not suggest (or expressly disclaims) such a patented use, it will be difficult to establish direct infringement. There are other means for investigation and analysing infringement of second medical use invention which are outside the scope of this article.

### **What is the Best Protection Strategy for Medical & Pharmaceutical Inventions in the GCC?**

The best protection strategy would depend on the facts of each case, and in particular on the nature of the invention, the main markets of the invention, the importance of the invention for the client's business, the budget and the protection strategy adopted for equivalent applications in foreign countries. While clients normally go through the PCT route abroad, we generally recommend filing a GCC patent application within the 12 months priority period as this is a cost efficient vehicle for seeking protection in all GCC member states. If the 12 months priority period has expired, then the national phase route can be considered by filing separate patent applications at the national patent offices where possible. Depending on the nature of the invention, including whether a second medical use is claimed and other factors, we may recommend a different or a backup protection strategy along with a customized prosecution strategy taking into consideration any relevant factors which may impact or leverage acceptance of the applications filed. GCC and national applications can coexist which can be used as part of the strategy. We normally work with clients to align the prosecution strategy for the GCC with their global prosecution strategy as GCC filed applications can be impacted by the examination outcome of equivalent applications filed abroad.

### **Final Comments**

As can be seen from the above, there is no single GCC approach to these issues and this can make it complicated and costly to seek patent protection across the GCC. Harmonization of GCC patent laws and the adoption of guidelines with respect to the patentability of second and further medical use inventions would be welcome and is achievable.

As matters currently stand, we encourage innovators to file patent applications covering second and further medical use inventions as the chances of securing patent protection for these are fairly good (provided the patentability criteria for novelty, inventiveness and utility are met). More applications will also increase awareness around the importance of such inventions for innovator companies and will help in weighing the balance in favour of further protection for such inventions during any future reviews of the law by the competent legal authorities.

### **How Can AI Tamimi Help?**

Our intellectual property department has a dedicated life sciences team which can assist pharmaceutical companies and other health care entities in a wide range of contentious and non-contentious legal services across the GCC region. For more information or questions, please contact Ahmad Saleh (Regional Head of Patents & Designs – R&D and Innovations) at [a.saleh@tamimi.com](mailto:a.saleh@tamimi.com) or Houda Meliani (Patent Agent, Ph.D. Chemistry) at [h.meliani@tamimi.com](mailto:h.meliani@tamimi.com).