Protecting medicinal and pharmaceutical products in the GCC: Originators Vs. Generics

Ahmad Saleh - Partner, Head of Innovation, Patents & Industrial Property - Innovation, Patents & Industrial Property (3IP)

ah.saleh@tamimi.com - Dubai International Financial Centre

UmmeSalamah Tyebjee

u.tyebjee@tamimi.com

The drug patent system in the GCC region is fairly robust and provides an expedient way for pharmaceutical entities to secure patent rights in the various GCC countries, thereby preventing generic companies from entering the pharmaceutical markets. Pharmaceutical products are particularly protected through the protection of novel chemical compounds, medical substances, pharmaceutical compositions, active agents, and other medical substances as well as through the protection of new and innovative processes used for obtaining such medicinal 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, increased bioavailability, and/or enhanced therapeutic efficacy. In most GCC countries (except Oman), methods of surgical or diagnostic, or therapeutic treatment on humans or animals are yet not considered patentable subject matter and cannot be pursued for patent protection.

Over the past few years, the GCC countries have updated and amended their patent laws, particularly aligning them with internationally recognised practices. Second medical use inventions and Swiss type claims, which were previously considered to not be patentable, are now allowed and accepted in most GCC countries. The patent laws of Oman and Bahrain specifically provide for the patentability of the second medical use of a known drug (compound or composition). Although not provided by law, the GCC Patent Office, along with the Saudi Arabia and the UAE patent offices, have recently started accepting patent applications with second medical uses, provided the pharmaceutical compound for which the second medical use is claimed to be novel.

Regulatory exclusivity – recognising patents of origin

Regulatory exclusivity is not recognised by the GCC countries. GCC countries require a pharmaceutical entity to have local patent protection for their drugs in order to prevent a generic from entering the pharmaceutical market and seeking a marketing authorisation from the relevant Ministry of Health. This means that even though a pharmaceutical entity has a valid patent in any other part of the world, they cannot claim the equivalent protection based on that patent (patent of origin) in the GCC countries.

In the past, the UAE did recognise patents of origin and allowed a pharmaceutical entity to claim equivalent patent protection to block the approval of a generic company attempting to seek marketing approval for the introduction of a generic competing drug in the UAE market (as per the Ministerial Decree 404 of 2000 ('Decree 404').

However, certain changes and uncertainties have arisen around the application of Decree 404 over the last couple of years; a new decree was issued on 21 September 2020 by the UAE Ministry of Health & Prevention ('MOHAP') under the name of Ministerial Decree 321 of 2020 ('Decree 321'). According to Decree 321, patents of origin are indirectly rejected as a means of protecting registered drugs inside the

UAE with the exception of products registered or which have obtained marketing approval from MOHAP before the date of publication of the Decree 321 in the UAE Official Gazette, which is expected to occur during October 2020. Decree 404 will however, continue to apply to drugs registered or approved before the publication date of the new Decree 321.

The Saudi Food and Drug Authority ('SFDA') published a consultation report in September 2020 for receiving recommendations and comments on certain procedures related to the protection and registration of pharmaceutical products. It is still to be seen how the new regulation will address patents of origin in KSA however, our expectation is that patent linkage will be rather limited to local patent protections valid inside KSA, either through a KSA patent or a GCC patent. Hence, in order to prohibit generics from entering the market, it is highly recommended that the product or drug be protected by way of registering its patent at the respective patent offices.

Data exclusivity

Patents and data exclusivity work in a correlative fashion but are distinctly different vehicles of protection from one another. Patents are granted by the patent office (of the country where the patent application is being filed) anywhere along the development timeline of a drug and may comprise a wide range of claims. Data exclusivity protects data submitted by the originator company in support of their innovator drug, which cannot be used by a generic company for seeking approval of an equivalent generic drug during the data exclusivity protection period. This can run concurrently with a patent or not. Data exclusivity is a statutory provision and is granted to a pharmaceutical entity for a new drug application when the statutory requirements are met. Data exclusivity provisions ensure a balance between novel drug innovation and generic drug competition.

Regulatory approval for pharmaceutical products requires pharmaceutical entities to furnish data about the efficacy and safety of their product to the respective regulatory authorities. Any pharmaceutical entity applying for such approval for the first time needs to provide detailed, substantial information in addition to the clinical test data pertaining to the product for which such an approval is sought.

Usually, generic companies that subsequently wish to seek approval for marketing a generic drug (same as that of the originator) rely on information filed by the originator pharmaceutical company that made the first application. In order to be able to benefit from the data provided by the originator in their regulatory filings for a particular medicinal product, a generic company must show that their product has the same qualitative and quantitative composition as that of the originator product and that the generic drug is the originator drug's bioequivalent. By providing data exclusivity, an originator company enjoys a particular stipulated period during which their pre-clinical and clinical trials data provided to the regulatory authorities for seeking an approval is kept confidential and is not to be referenced in the regulatory filings of another company (typically a generic company) for the same drug substance.

Some of the GCC member states also provide for provisions of data exclusivity in their laws. Amongst the various GCC countries, the United Arab Emirates, Saudi Arabia, Oman, and Bahrain provide for such data exclusivity provisions in their laws. Generic companies, prior to applying for marketing approvals from the relevant ministry of health, must ensure that there is no valid patent protection in that country for that particular drug.

The recognition of data exclusivity by some of the leading GCC countries, in addition to the robust patent laws, has led to a tremendous increase in the number of pharmaceutical patents being filed in the region. Each GCC country has its own regime with respect to the protection of clinical data submitted by originators, and patent linkage.

Pharmaceutical registration and marketing approvals

In the GCC countries, importation and distribution of pharmaceutical products, be they originator drug or generic, is subject to the supervision and approval by the relevant governmental entity in each country, namely the relevant ministry of health, food and drug administration or authority, or other authority depending on the country. The GCC does not have a centralised governmental body regulating the importation and distribution of pharmaceutical products inside the region, and therefore marketing approval must be sought separately for each one of the GCC countries according to applicable national laws and regulations. In general, and subject to limited exceptions, no pharmaceutical product, whether an originator or a generic product, can be marketed, distributed, sold, offered for sale, and/or imported without seeking prior approval for the same from the relevant authorities, and registration of a pharmaceutical drug with the relevant ministry of health is generally mandatory, irrespective of whether such a drug is protected by a patent. We believe that GCC countries will be taking increasing measures for balance patent protection and generic entry through the introduction and regulation of patent linkage processes and systems.

Prior to seeking or applying for such marketing approvals, generic companies must ensure that there is no valid patent covering the drug product for which they are seeking marketing approval.

Pharmaceutical patent enforcement

Pharmaceutical patent enforcement in the GCC is governed through local federal courts and by the patent laws of the respective GCC countries where the infringement activity is taking place. There are no unified courts relating to GCC patent matters. The authorities of each GCC member state must examine all disputes relating to infringement or imminent infringement of pharmaceutical patents and such disputes must be settled in accordance with the provisions of the local patent laws and regulations governing national patents (if any). During patent enforcement and litigation, it must be noted that courts of the various GCC countries may take into consideration decisions from foreign courts or international bodies specifically for cases relating to the technical subject matter. However, the local courts are not bound by these decisions.

Enforcement of patents in the region, as is the case in all emerging and developing countries, requires a steep learning curve and is often met with certain challenges, some of which are the country’s limited expertise in dealing with patent cases, lack of precedents, lengthy proceedings, absence of awards for indirect damages, high costs of translations, and other legal formalities.

In the past several years, the GCC countries have come a long way in enforcing their patent laws and making sure that the patent rights of owners are protected in the market. But what remains to be done is to develop specialised courts with a specific focus on patent litigation and infringement matters. Although, at present, the overall regional experience with infringement and litigation regarding patent applications is small, the same is expected to rise in the near future considering that the authorities of these countries are actively working towards the development of specialised courts, legal advisors, and judges to handle and preside over patent litigation matters.

Conclusion

The goal of the patent laws and data exclusivity provisions in the GCC region is to mainly allow the originators to recoup their heavy R&D investment and prevent the generics from entering the

pharmaceutical market and consequently drive down the market prices during the lifetime of their patents. Through patenting or data exclusivity, the originator or pharmaceutical companies today have the option of safely and securely penetrating the rapidly growing pharmaceutical market of the GCC region. The new Decree 321 and the consultancy document issued by the SFDA in September 2020 are aligned to set a fair balance between a strong IP regime protecting the interests of innovators and originators and a generic pharma market with an enhanced regulated and transparent marketing penetration process and rules.

As matters currently stand, we encourage pharmaceutical originators to file patent applications covering their drug products or composition's inventions as the chances of securing patent protection for these are fairly good, in addition to excluding the generic companies from marketing and distributing the drug in the market. More applications will also increase awareness around the importance of such inventions for originator 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.

For further information, please contact healthcare@tamimi.com.