Vaccine Patents and Legal Framework in the UAE

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*This illustration is inspired by the original painting of **American Gothic** by Grant Wood.*

Pharmaceutical products can be incredibly time consuming and costly to develop. Pharma companies often bear losses when they undertake research and development to produce vaccines. Consequently, the prices of vaccines must be set at a level to help companies not only recoup their investments in developing a successful vaccine, but also to compensate them for any losses suffered in the failed pursuit of finding treatments for other illnesses. One of the goals of a patent system is to incentivise innovation. It is the intellectual property behind vaccines that enable pharma companies to seek to recover their investments, as a robust patent system will exclude others from creating the same product, for a period of time, or protect the knowledge on how to recreate the product.

The patent system, as it is currently designed, may at times collide with access to treatment, particularly in times of a pandemic or other situations concerning public health. In order to prevent this conflict, the patent system has in place certain mechanisms and procedures that allow third parties, including governments, access to vaccines protected by patents.

This article addresses some of the common questions we receive from clients in relation to the legal framework for vaccine regulation in the UAE, patenting of vaccines, and the mechanisms in the UAE Patent Law for mandatory licensing of vaccines in case of public health emergencies.

Legal Framework of Vaccine Regulation in the United Arab Emirates

The UAE life sciences industry is primarily regulated at the federal level by the Federal Ministry of Health and Prevention ('**MOHAP**'), with MOHAP having authority over pharmaceuticals, vaccines, and biological products, other medical products, and medical devices.

While MOHAP is the authority granting approvals of and regulating the importation and distribution of vaccines in the UAE, the individual emirates of Dubai and Abu Dhabi will from time to time pass regulations concerning the administration of such vaccines at healthcare facilities within their emirate, but do not have primary authority concerning the approval for the vaccine to be imported, distributed, marketed, and sold in the UAE, as this primary authority falls to MOHAP.

Vaccine Patents

Patents are an incentive to invent or innovate. Vaccine patents in the UAE are regulated under Federal Law No. 11 of 2021 ('**Patent Law**'), and are assessed in the same way as inventions in other areas, provided they meet the patentability criteria (i.e. novelty, inventive concept, industrial applicability). Patent protection in the UAE is granted for each new invention resulting from an innovative idea or innovative improvement that involves an inventive step and is capable of industrial application.

Patentable inventions related to vaccines predominantly cover the active ingredient (antigen, antibody), derivatives thereof, combinations, formulations, compounds and/ or methods of production of the vaccine in itself.

Use claims in relation to novel and inventive compositions are normally allowed, however some examiners associate these to methods of treatment and reject them as such. Swiss-type claims related to secondary medical use are more likely to be rejected when the original composition is not novel, however there have been occasions in the past where these claims were accepted by some examiners. Method of treatment related claims are not accepted in UAE and this is specifically prohibited under the legislation.

Data Exclusivity for Vaccines

Patents and data exclusivity work in a correlative fashion but are distinctly different from one another. Data exclusivity is predominantly exclusive marketing rights granted by the MOHAP upon approval of a vaccine and can run concurrently with a patent or not. Data exclusivity is a statutory provision and is granted to a pharmaceutical entity for a new vaccine application when the statutory requirements are met. Data exclusivity provisions ensure a balance between novel innovation and generic competition.

The UAE provides regulations to protect and keep confidential all test and clinical data for vaccines submitted to government authorities at the time of seeking approval for vaccines. This is governed by the Ministerial Decree 321 of 2020 ('**Decree 321**') issued by the MOHAP.

The data exclusivity period under Decree 321 is set to eight years from the date of seeking marketing approval from MOHAP ('**MOHAP**'). There may be certain exceptions where the Ministry may reduce the data exclusivity period for public health or other reason, which are decided on a case-by-case basis.

It is worth noting that the Data Exclusivity Period is granted to a company irrespective of whether they have valid patent protection in the UAE. Absent a patent protection. a generic company can apply for marketing approval within the last two years of the Data Exclusivity Period.

Licensing and Importation of Vaccines in UAE

MOHAP has put in place emergency use authorisation ('**EUA**') guidelines allowing a faster review process. Amongst other requirements, EUA is permissible only after there has been a declaration by a global health authority of an emergency leading to a serious or life-threatening disease or condition.

Prior to the importation or licensing of vaccines or vaccine related technologies in the UAE, the vaccine must be approved by and registered with MOHAP. In order to import a vaccine or vaccine related products into the UAE, the importing company must be an entity established in the UAE and licensed by MOHAP to import vaccine or vaccine related products into the UA.E Foreign companies wishing to import such products into the UAE have the options of either

- incorporating a UAE entity and undertaking the licensing process with the MOHAP through this locally licensed entity; or
- engage with a local UAE distributor or agent ('**Distributor**'), who is already licensed through the MOHAP and, through the Distributor, register the vaccine product within the country.

In order to seek the marketing approval for a vaccine in the UAE, the foreign vaccine manufacturer along with the Distributor must jointly submit an application to MOHAP. The application must provide information about the product, such as test data, certificate of Good Manufacturing Practices, and certificate of pharmaceutical product, and pricing related data, (if required, composition certificate, packaging and storage requirements, in addition to quality, non-clinical, and clinical data).

Other information required includes an audit plan, details concerning the manufacturing site of the products, information regarding the usage of the product, precautions while using the product, post-marketing strategies, safety information, and labelling. Upon receiving the application, MOHAP will review the application and the documents attached therein and may request additional information from the applicant. If all requirements are met, MOHAP will grant the required approvals.

It is recommended to have a commercial agency agreement, executed between the foreign vaccine manufacturer and the Distributor, regarding the supply and, if applicable, technology/know-how being transferred. The licensed Distributor will act on the behalf of company to import and distribute the products in the UAE, and often will also market the products, depending on the agreement between the foreign manufacturer and the Distributor.

Following importation, both the foreign manufacturer and Distributor have a number of ongoing obligations. For instance, MOHAP has issued Good Pharmaceutical Storage and Distribution Practices ('**GS&DP**'), which should be incorporated into the quality management system. The GS&DP seeks to assure the quality of the regulated product through controlling various activities related to storage and distribution operations procedures. The foreign manufacturer and its Distributor have an ongoing duty to monitor the market and their products; accordingly, MOHAP should be informed of any significant change(s) that could reasonably be expected to affect the safety or effectiveness of a vaccine.

Further, MOHAP published the UAE MOH Guidelines in Good Vigilance Practice ('**GVP**'), for Distributors and

pharmaceutical manufacturers. The GVP addresses the requirements, as regards the collection of information, data management, and reporting of suspected adverse reactions (serious and non-serious) associated with medicinal products for human use authorised in the UAE.

Compulsory Licensing of Vaccine Patents during public health emergencies

There has always been an ongoing debate about vaccines and the intellectual property rights associated with the same. A vaccine patent in the UAE will give the patentee an exclusive right to manufacture, sell, import, and offer to sell the vaccine for a period of 20 years, excluding third parties from doing the same. In order to ensure the UAE population has access to critical treatments, the patent system has in place certain mechanisms and procedures that allow third parties, including governments, to access vaccines protected by patents. One such mechanism is compulsory licensing of vaccine patents, whereby the government allows a third party to produce a patented vaccine without the consent of the patentee.

The UAE Patent Law provides for compulsory licensing of patents, detailing the requirements, scenarios, procedures, and exceptions for the granting of a compulsory licence. In the UAE, compulsory licences are granted by a decision of the Minister of Economy, when a patentee does not sufficiently exploit the invention for a period of at least three years from the date of being granted a patent. A compulsory licence is usually granted for inventions that may have a significant contribution to the public interest. Any interested party may obtain a compulsory licence, provided the conditions of the Patent Law are met.

An exception to the above is when a compulsory licence is granted in case of a general emergency or by a highly urgent public health need. In such an event, there is no need for three years to pass from the issuance of the patent or for the interested third party to show that it made efforts to obtain a licence from the patentee under reasonable commercial conditions. Some of the conditions that must be met for a compulsory licence to be granted in case of an emergency include the following:

- The licence should not be absolute;
- The licence must be intended to satisfy the requirements of the local market;
- The patentee should be awarded fair compensation; and
- The use of the patent is restricted to the licensee. The licence cannot be transferred to a third party except where the ownership (or part) of the licensee entity has been assigned. Such a transfer must be approved by the UAE Court.

Currently there are no cases of patents being licensed compulsorily in the UAE.

Are there any special regulations on intellectual property rights relating to vaccines?

At this time, no special regulations on intellectual property rights relating to vaccines have been enacted in the UAE. The UAE government has not made public statements regarding the exemptions to intellectual property rights in relation to vaccines.

Conclusion

In view of the Covid- 19 pandemic, there has been an ongoing debate on the temporary suspension of intellectual property rights pertaining to vaccines in order to enhance public access to vaccines. This would mean generic, or otherwise non-licensed, manufacturers could begin production of patented vaccines in the countries considered to have the production capacity to do so. Pharmaceutical companies have opposed this, arguing that suspension for patent protection on vaccines would stifle innovation.

There is no doubt that pharmaceutical companies invest heavily in terms of both money and research in manufacturing viable vaccines and patent protection is a way to recoup not only the investments but also compensate for the losses suffered during the research and development process. Waiving intellectual property rights for vaccines during a public health emergency should not be considered a standalone solution to maximise vaccine production. Patent protection may form one part of the ongoing debate on accelerating vaccine production and rollout, but removing these protections looks unlikely to resolve other regulatory and political barriers that have proven important in ensuring global access to vaccines.

Governments should look into other mechanisms to increase vaccine production and roll out during public health crises that balances the needs of both the pharmaceutical vaccine manufacturers and the public.

How can Al Tamimi Help?

Our Innovations and Patents department has a dedicated life sciences team capable of assisting life sciences 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 (Partner, Head of Innovation & Patents) at ah.saleh@tamimi.com and Umme Salamah Tyebjee (Associate) at u.tyebjee@tamimi.com.

Al Tamimi & Company's Innovation and Patents team regularly advises 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 (Partner, Head of Innovation & Patents) at ah.saleh@tamimi.com or Umme Salamah Tyebjee at u.tyebjee@tamimi.com.