Vaccine Patents and Legal Framework – A KSA perspective

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

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

Christina Sochacki - Senior Counsel - Corporate / Mergers and Acquisitions

c.sochacki@tamimi.com - Jeddah

Umme Salamah Tyebjee - Senior Associate - Innovation, Patents & Industrial Property (3IP)

u.tyebjee@tamimi.com - Dubai International Financial Centre

Imad El Ess - Associate - Innovation, Patents & Industrial Property (3IP)

i.eless@tamimi.com - Riyadh

Vaccinations are critical to population health; every year, they prevent up to 3 million deaths worldwide. Policymakers and public health officials are increasingly focusing on ways to accelerate the pace and maximize the extent of vaccine uptake. These efforts include providing for emergency use authorisations and mandatory licensing of vaccines to increase vaccine supply.

Undoubtedly, the novel pandemic and the economic impact of lock-down or shelter-in-place orders create new risks every day. One risk to pharmaceutical, life sciences, and other health care technology companies is the risk that the patents related to treatments and vaccines developed may be suspended or involuntarily licensed to governments, and even competitors. Assessing these risks, the impact that compulsory licensing may have on investments in research and new product development, and the potential for compulsory licenses to result in the loss of intellectual property rights, is essential to any business strategy for companies developing technology-related treatments.

This article addresses some of the common questions concerning the legal framework for vaccine regulation in the Kingdom of Saudi Arabia ('**KSA**' or '**Saudi Arabia**'), patenting of vaccines, and the mechanisms in the Saudi Patent Law for mandatory licensing of vaccines in case of public health emergencies.

VACCINE PATENTS

What is a vaccine patent?

Like other types of pharmaceutical products, patents can protect new innovative vaccines in order to protect these from unauthorised reproduction by competitors. Patentable inventions related to vaccines predominantly cover the protecting of the active ingredient (antigen, antibody), derivatives thereof, combinations, formulations, compounds, and/ or methods of production of the vaccine in itself.

Vaccine patents in the Kingdom of Saudi Arabia are regulated under the Law of Patents, Layout- Designs of Integrated Circuits, Plant Varieties, and Industrial Designs (**'KSA Patent Law**'").

How much time does it take to examine and grant a vaccine patent? Do any mechanisms exist to expedite patent examination?

The approximate time- frame for a vaccine patent to be granted is two to four years from the date of filing the application in KSA. This time- frame can vary depending on the length of prosecution and the

complexity of the subject matter claimed.

Applicants can opt for expedited examination under the Saudi Patent Prosecution Highway ('**PPH**') program. The PPH is present in Saudi Arabia – between the Saudi Intellectual Property Authority ('**SAIP**') and four Patent offices, namely the USPTO, Korean Patent Office (KIPO), Chinese Patent office (CNIPA), and the Japanese Patent Office (JPO). This program commenced on 01 January 2020, for a duration of three years, and will end on 12 December 2022.

What advantages does a vaccine patent provide?

Having a local patent protection for a vaccine offers the patentee a legal monopoly to manufacture, sell, import, and offer to sell the vaccine for a period of 20 years, excluding third parties from doing the same.

Further, having a local patent protection in Saudi Arabia will also prevent a generic company from obtaining marketing approvals for the patented vaccine and thereby prevent the entry of the generic into the Saudi pharmaceutical market. The Saudi Food and Drug Authority ('**SFDA**') (the regulatory authority for all pharmaceuticals and medical devices), will not grant marketing approvals to a generic company if there is a valid patent in force in Saudi Arabia for the originator vaccine.

Patents of origin are not recognized in Saudi Arabia. This means that even if a pharmaceutical entity has a valid patent in any other part of the world, they cannot claim equivalent protection based on that foreign patent in Saudi Arabia.

What are the conditions of patentability? How critical is it to disclose data within the application as original filed? In the absence of data being disclosed within the application, is it possible to submit data during examination (post- filing) to support patentability?

Vaccine related inventions much be novel and inventive in order to be patentable. In addition, the patent applicant must provide a sufficient disclosure of the invention.

It is recommended to submit test/ clinical/ experimental data in the application as filed for enablement of the invention. In case such data is not disclosed in the application, the same can be submitted as supporting evidence at the time of prosecution/ examination of the application. However, the patent office must normally ensure that such data is supported by the as filed specification. Thus, the acceptance and consideration of such data and allowance of the application based on such additional data submitted (not originally disclosed in the specification) is at the discretion of the Patent Examiner.

COMPULSORY LICENSING

Can a third party seek a compulsory license to exploit a patented vaccine in KSA? If yes, what are the grounds for obtaining a compulsory licensing?

Yes. The KSA Patent Law provides for compulsory licensing to allow third parties, including governments, to access vaccines protected by patents, without the consent of the patentee. Compulsory licences are granted by a decision from the SAIP. Any interested party can apply for a compulsory license, 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 or four years from date filing the application in KSA, whichever expires later.

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.

Are there any exceptions to the issuance of a compulsory license in KSA?

In principle, the compulsory license will not be granted unless the applicant has made efforts to obtain a license from the proprietor on reasonable commercial terms and conditions and established that their efforts have not been successful within a reasonable period. An exception to the above is when a compulsory license is granted in case of a general emergency or by a highly urgent public health need. In such a case, SAIP may grant a compulsory license to a government entity, to meet a state of emergency or other compelling circumstances, for non-commercial purposes and public benefit.

IMPORTATION, DISTRIBUTION AND MARKETING APPROVAL OF VACCINES

Who can import and distribute a vaccine in the KSA market?

- **When the vaccine manufacturer is a local entity**

In order to distribute vaccine or vaccine related products into KSA, the distributing company must be an entity established in KSA and must be registered with the SFDA. No vaccine product can be marketed, distributed, sold, offered for sale and/ or imported without seeking prior approval for the same from the SFDA.

- **When the vaccine manufacturer is a foreign entity**

Foreign companies wishing to import and distribute vaccines or vaccine related products into the KSA have the options of either:

1. incorporating a KSA entity and undertaking the licensing process with the SFDA; or
2. engaging with a local distributor or agent, who is already licensed through the SFDA, and registering the vaccine products within the country. The local distributor must be either a Saudi national or a wholly owned Saudi entity. The local licensed distributor will act on the behalf of the foreign manufacturer to import, distribute and market the products in KSA.

In both the above mentioned scenarios, a marketing approval to import, distribute, or sell the vaccine or vaccine related product needs to be sought from the SFDA. No product can be marketed, distributed, sold, offered for sale and/ or imported without seeking prior approval for the same from the SFDA.

What is the procedure to seek marketing approval for a vaccine?

For seeking such approval, an application must be submitted to the SFDA by the local distributor/ agent for their perusal and approval. The application must mention details about the product such as the relevant test data, certificate of Good Manufacturing Practices, and certificate of pharmaceutical product, pricing related data, (if required composition certificate, packaging and storage requirements in addition to the quality, non-clinical, and clinical data) and vaccine samples. Recently, the SFDA has been requesting generic companies to submit a patent statement as part of their requests providing all relevant information proving the non-existent of valid patents covering the original pharmaceutical and undertaking not to infringe any such patents. Additionally, companies seeking marketing authorization may also be required to submit an audit plan, details concerning the site for manufacturing products, information regarding the usage of the product, precautions while using the product, post-marketing strategies, safety information, and labelling. Upon receiving the application, the SFDA will review the application and the documents attached therein. They may further seek additional documents from the applicant if required.

The time-frame required to obtain marketing approval is approximately 1- 1.5 years from the date of submitting the application.

Can a vaccine manufacturer apply for marketing approval, prior to grant of a vaccine patent?

- **In case of an originator**

Yes. A vaccine manufacturer can apply for marketing approval, pending the grant of a patent.

- **In case of a generic**

In case a generic manufacturer applies for a marketing approval, pending the grant of a patent, the SFDA will most likely will postpone its decision to grant the marketing approval to the generic until a decision on a patent application is reached. In case the patent is rejected, the SFDA will proceed to grant the marketing approval to the generic vaccines, if it meets all other requirements. In the event the patent is granted, the SFDA will keep the application on hold and postpone its decision to grant the marketing approval to the generic vaccine product until expiry of the said patent.

Can a generic company apply for marketing approval while there is a valid vaccine patent?

A generic company can apply for a marketing authorization for a generic vaccine product within the last two years before the expiration of a valid patent for the originator product. The SFDA may grant the marketing authorization to the biosimilar product under the condition that import and commercialisation of the drug takes place after the expiry of the said patent. The SFDA may call the originator company to confirm the patent coverage over the generic and confirm the patent term coverage.

Is there a patent linkage between the SFDA and SAIP?

No, currently there is no patent linkage between both systems. A generic company applying for marketing approval in front of the SFDA must provide a patent statement as part of the marketing request proving that there are no patents covering the original drug in force inside the Kingdom.

DATA EXCLUSIVITY

Can a generic company access the clinical trials and other data submitted by the vaccine manufacturer to the SFDA during the marketing approval process?

No. KSA also provides for regulations to protect test data submitted to SFDA at the time of seeking approval of vaccine products. As per the Regulations for the Protection of Confidential Commercial Information, Saudi Arabia recognises the concept of data exclusivity and requires governmental authorities to not disclose and to keep secret any test data submitted to them for seeking marketing approval for an originator drug, for a minimum period of five years (‘**Data Exclusivity Period’**) from the date of obtaining the approval. The maximum period of keeping such data confidential is not mentioned under the Regulation and depends on the discretion of the SFDA.

It is worth noting, the Data Exclusivity Period is granted to a company irrespective of whether a company has a valid patent protection for that particular product in Saudi Arabia.

CONCLUSION

Saudi Arabia, being one of the fastest growing markets for pharmaceutical products, especially vaccines, offers a lucrative opportunity for pharmaceutical companies to market and distribute vaccines in this region. The goal of the patent laws and data exclusivity provisions in KSA are to mainly prevent generics

from entering the pharmaceutical market and driving the prices down and thereby encourage innovative medicines to enter the Saudi market. It is the intellectual property behind vaccines that enable pharmaceutical 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.

As matters currently stand, we encourage vaccine originators innovators to file patent applications covering their vaccines and vaccine related products as these are eligible subject matters for patentability there which, once they are granted patents, allow for excluding others from marketing, importing and distributing similar versions of the drug in the market.

Considering the high costs involved for the preparation and submission of marketing approval requests and the likelihood of rejection of the approval owing to pending patent applications or valid patents being in force in KSA, generic companies, are recommended to conduct patent clearance searches as well as to secure agreements or non-objections with the originator companies, where possible, prior to applying for marketing approvals.

For further information, please contact Ahmad Saleh.