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A rapidly growing Biopharma market

Namir Sioufi, **Saba IP**, explores patent law in the MENA region in relation to the growing Biopharma market, looking closely at the similarities and differences of the regions involved.

The Middle East and North Africa, simply referred to as MENA, has several characteristics as a region to attract the pharmaceutical industry. The population is expanding and aging at a rapid rate, the region as a whole is experiencing a large unmet medical need, the change in socio-economic status is witnessing a growing middle class, and lastly, the desire and the ability to pay for branded and generic therapies.

Pharmaceuticals market in the MENA

In 2015, BioWorld™ published a series of articles as part of a special report about the MENA region. The report identified certain countries as rivaling some of the BRIC countries, namely Algeria, Egypt, Morocco, Saudi Arabia and the United Arabic Emirates (UAE). At the time, the report identified the region with a population of 350 million, a GDP of about $2 trillion and a pharmaceutical market estimated at $18 billion with an annual growth rate of 8 percent.

The actual compound annual growth rate (CAGR) for the Algeria, Egypt and the Gulf Cooperation Council (GCC) countries ranges between 12 and 15 percent. In comparison, the CAGR for developed markets is between 1 and 4 percent. These values are driven by an increase in age-related diseases of a growing population. Statistics indicate that Saudi Arabia, for example, has overtaken countries such as France and the USA in incidence of diabetes and obesity (Source: Boston Oncology LLC). Studies have shown that both conditions have been linked to a higher risk for cancer. Accordingly, the incidence for all three conditions is expected to continue growing, fueling a steadily increasing market.

Today, at over $20 billion, the pharmaceuticals market in the MENA offers a lucrative opportunity to pharmaceutical companies. Patented drugs make up anywhere from 60 to 80 percent of the pharmaceuticals market in total sales. The general trend is that the richer the country is, the higher the patented drug market share is. It is projected that the total market size will grow to just over $30 billion by 2018.

Based on these numbers, the MENA is an exceedingly attractive market for innovator companies to consider when deliberating an international expansion. With patented drug sales of approximately $2 billion and $4 billion respectively, Egypt and Saudi Arabia are the two largest markets. Egypt is a relatively poor country but with the largest population in the MENA region at close to 85 million; Saudi Arabia, with a population estimated at 28 million, is one of the wealthiest countries in that same region.

	Patented drugs	Generic drugs
Saudi Arabia	80%	8%
Bahrain	80%	6%
Jordan	50%	33%

In Saudi Arabia, patented drugs account for over 80 percent of pharmaceutical sales, whereas generic drugs account for less than 8 percent. Another example with high patented drug sales is Bahrain, where the numbers in this case are approximately 80 percent for patented drugs and less than 6 percent for generic drugs.

Jordan, on the other hand, is the only country in the region where total sales of generic drugs are higher than for patented drugs. In Jordan, generic drugs account for nearly 50 percent of total sales, whereas patented drugs account for about 33 percent. This is a result of a strong and well-organized local pharmaceutical industry and a relatively low healthcare purchasing power. While Jordan's current patent law provides a 20-year patent-term and a market exclusivity period, one key aspect of the law that alleviates pressure on the local industry is the Bolar exception. This allows firms to develop and test a generic drug during the period of market exclusivity, and thus ensure timely delivery of a generic upon patent

Résumé

Namir Sioufi

Namir joined Saba IP in 2012 and currently manages the Patent Department at the Head Office. He works alongside a team of professional experts with various specialized backgrounds and provides technical and legal support across all Saba IP branch offices.

Namir and his team manage several key patent portfolios from pre-filing recommendations and strategy through prosecution and grant. He has participated in several Global IP conferences as an attendee or a presenter.

Saba IP is the oldest and leading IP firm with offices throughout the Middle East and North African countries. They provide all types of IP-related services including prosecutions, procurement and litigation.

expiry. This provision, combined with the highly educated Jordanian pharmaceutical workforce, has also led to an increase in foreign investment in this sector. The Jordanian Patent Law is currently undergoing certain amendments, which would create more visibility on the patent landscape in the country for both patent owners and generic pharmaceuticals.

In more recent years, the local pharmaceutical industry has witnessed many developments. Driven by two main factors, the industry is developing to fill-in certain needs for the region.

The growing need for access to cheaper medicines, even in the oil rich countries, has driven local manufacturers to expand their capabilities and broaden their product offerings, including into filling the need for more accessible biosimilars. Where the capability is weak, local manufacturers have reached out to, and negotiated deals with, more advanced generic countries such as India to facilitate these countries' access to these lucrative markets and benefit from a broader and more advanced offering.

The second driving factor is the region's need to diversify its economy, in particular oil reach countries that have seen this necessity with the recent drop in oil prices. This need is driving the region to seek greater innovation, thus channeling more investment into Universities and innovation hubs. With a well-established pharmaceuticals industry, an increase in investment in innovation centers – such as The Qatar Foundation (Doha, Qatar), King Abdullah University of Science, and Technology (KAUST; Thuwal, Saudi Arabia) – and the need to address the needs of a growing middle class, the region is expected to witness an explosion in innovation over the coming years.

Patenting in the MENA

Over the past several years, almost every country in the MENA region has updated, revamped or introduced new patent laws; with many adopting internationally accepted practices. While in the past only pharmaceutical processes were patentable, it is now possible to patent pharmaceutical products or substances. In most cases, only new chemical entities are patentable, while in others, second medical use is allowed. In a few countries, patent term extension is possible if certain conditions are met. Morocco is an example where a supplementary protection certificate is issued for a period covering the number of days of delay in the event of unjustified delays by the authorities in awarding the authorization for marketing approval.

The number of MENA countries with PCT membership is increasing, alongside trade agreements between those countries and the US or Europe. These afford better prospects for businesses looking to penetrate new markets with growth opportunities. TRIPS or TRIPS like agreements exist in almost every country in the Middle East. The only two exceptions are Iran and Algeria, which have not yet signed such agreements but will be expected to as the need to see more foreign investments channeled their way.

Procedures at different patent offices vary substantially. In many countries, substantive examination as to novelty, inventiveness, and applicability is performed locally. In some countries, the same is outsourced to foreign patent offices. What is allowed under each local patent law also varies. In Egypt, it is not allowed to claim method of treating or use of a product, be it to diagnose, treat, or prevent. The Egyptian Patent Office does not even allow Swiss-type claims. Overall, the region has moved to allow almost all types of patents with the exception of methods of treatment or diagnosis.

The Arabian Gulf Countries had created in the 1990s a Gulf Cooperation Council (GCC) committee, which led to the creation of a regional GCC Patent Office (GCCPO) and the GCC Patent Law. A patent application filed with the GCCPO designates by default Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and the UAE. Once granted, a GCC patent is enforceable in all six named countries, without the need for further validation in each country or payment of separate annuities. The GCCPO offers a convenient alternative to filing six separate applications. Nevertheless, depending on the filing strategy, an applicant may very well choose national stage filings via the Patent Cooperation Treaty in the countries of interest such as the UAE and Saudi Arabia.

Enforcement of patents in the region, as is the case in all emerging and developing countries, requires a steep learning curve. Based on the teachings from other IP matters, in particular trademarks, the laws in place are sufficient to enforce a patent owner's legal rights. It is expected that specialized courts, lawyers, and judges see the light of day in the years to come as these are being worked on actively.

The overall region experience with infringement and litigation on patent applications is still small but expected to rise. The main reasons, as described above, are the need for more affordable medicines and the aggressive growth of the local generic industry.

Navigating the MENA market

Governments have to find a balance between foreign investments and the protection of their existing industry. In oil-rich countries, such as Saudi Arabia, non-oil industries may be marginal, yet a rapidly growing market exists for the pharmaceutical sector. For oil-poor countries, such as Jordan, the local pharmaceutical industry contributes considerably to the national GDP and plays a pivotal role in keeping healthcare cost low in such an economy. Understanding these dynamics is crucial when building a market strategy – especially in identifying needs for intellectual property protection.

Whether the goal is to exclude rival innovator companies or to prevent imitators – generics – from entering the market and driving prices down, patent laws and regulations in the MENA region increasingly offer better protection. Through patenting or data exclusivity, innovator pharmaceutical companies today have the option of safely and securely penetrating the rapidly growing market of the MENA region. The necessary laws have been drafted and are being enforced gradually. Amendments to drive foreign investments, as well as enhanced enforcement are being provided as needed. Lastly, the legal environment, while still unproven, seems to be maturing in the right direction.

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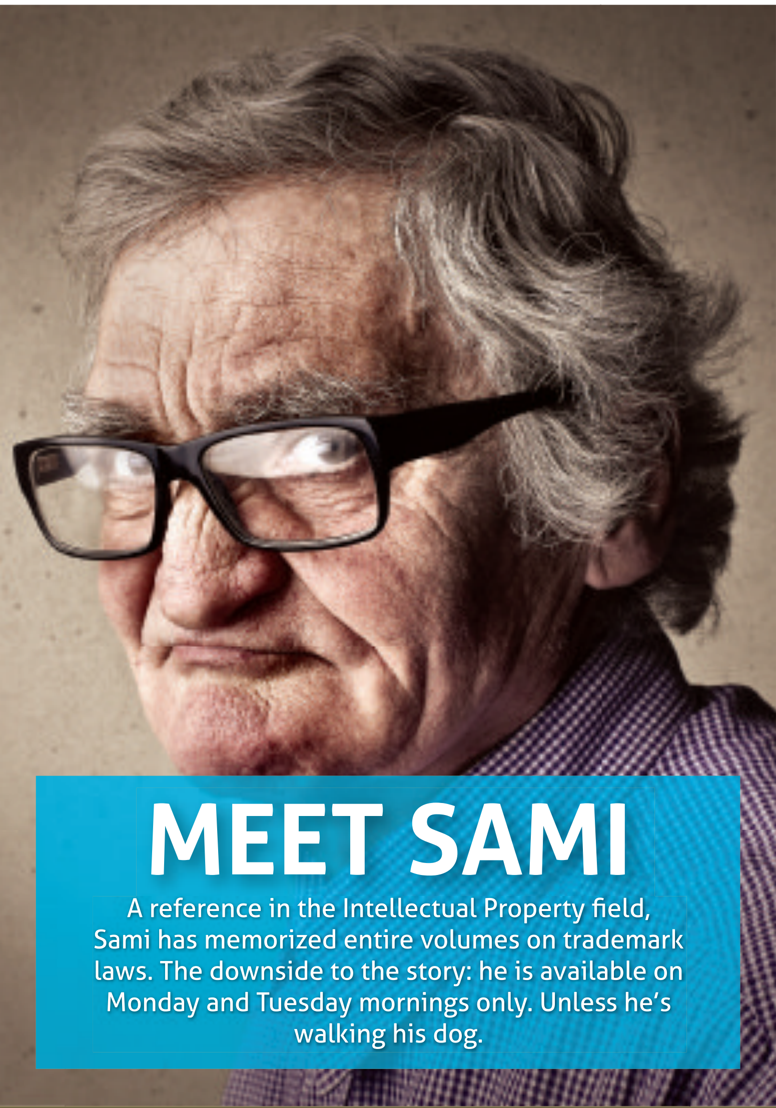

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