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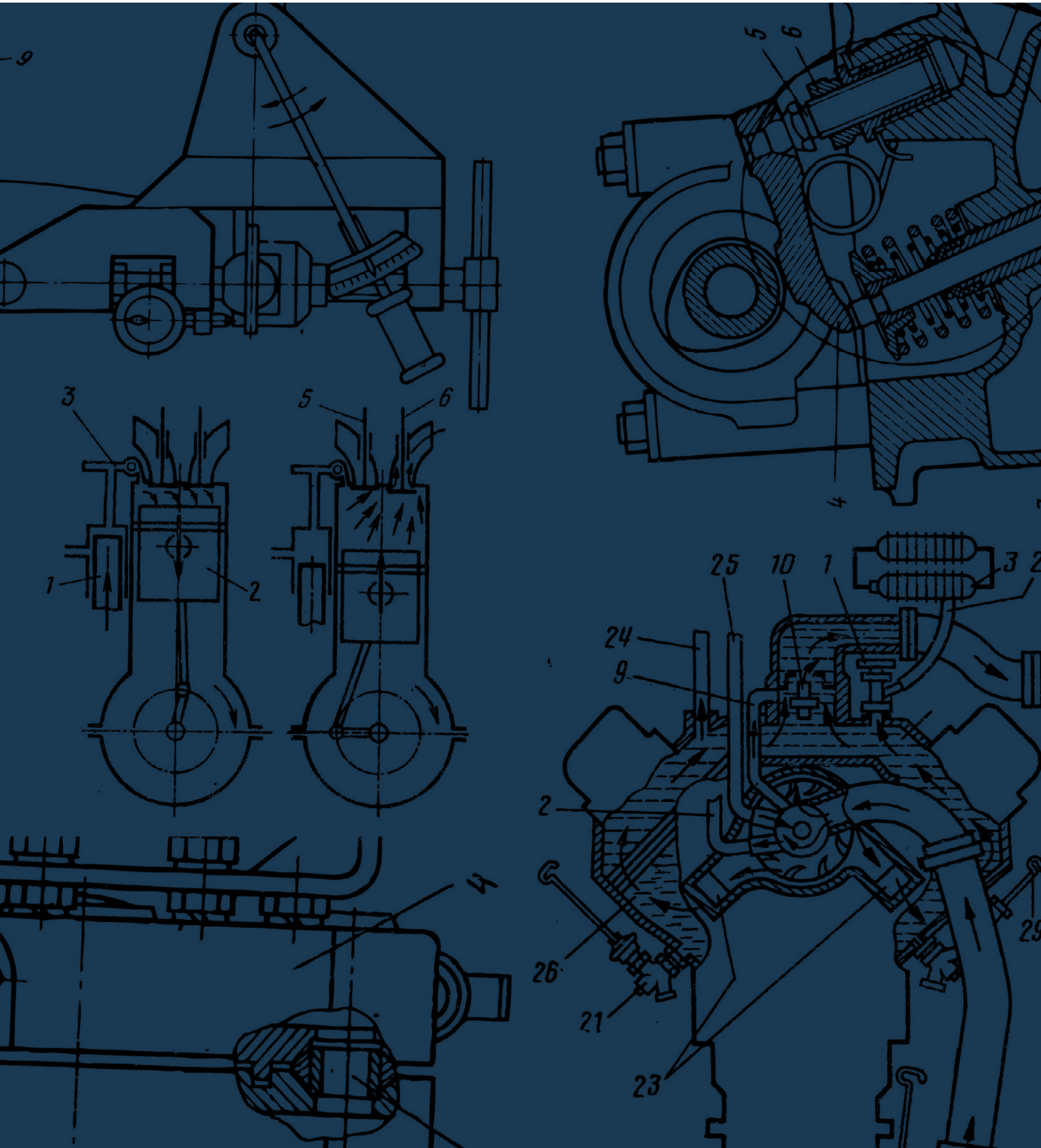

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PHARMA FOCUS: IN THIS ISSUE

MENA

Evaluating Risks and Opportunities for Pharmaceutical Patenting

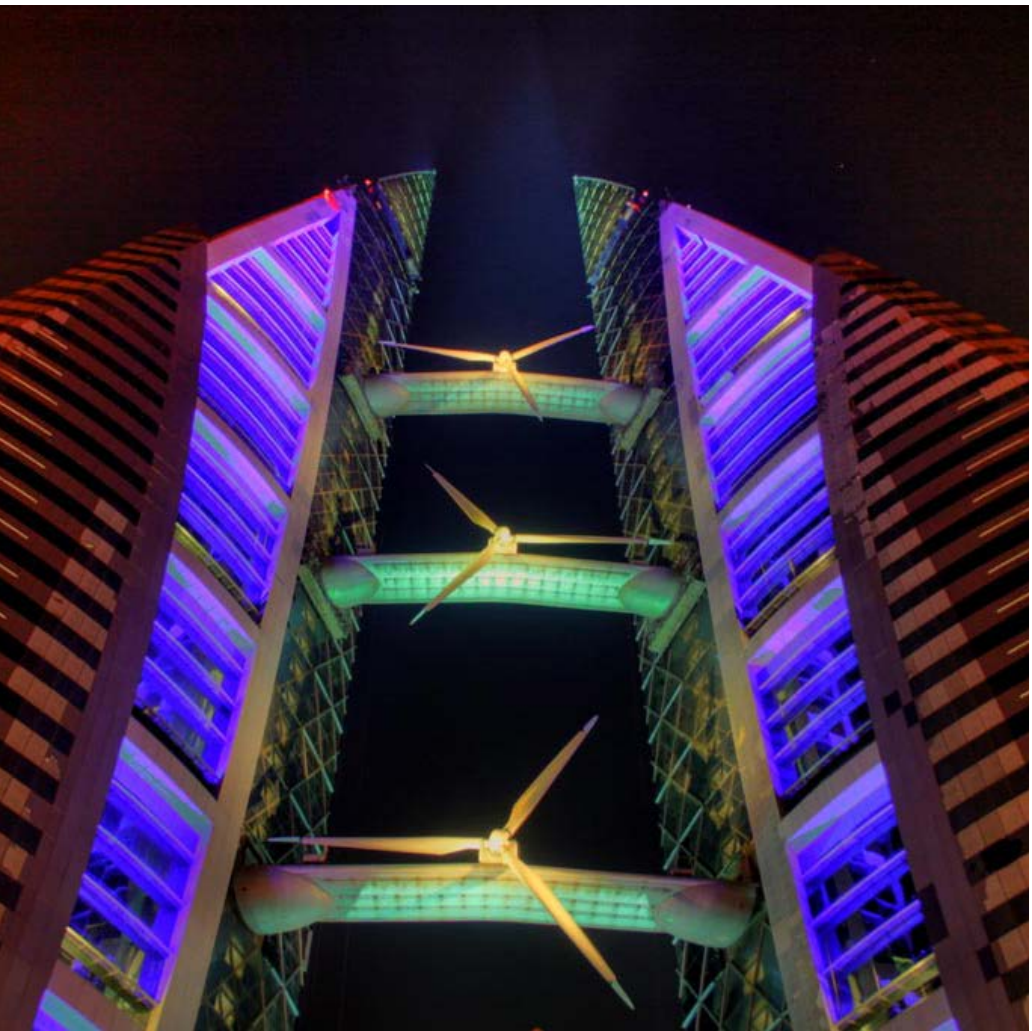
Navigating Pharmaceutical Trademark Protection

MENA: EVALUATING RISKS AND OPPORTUNITIES FOR PHARMACEUTICAL PATENTING

Three primary criteria exist for a pharmaceutical company to examine when formulating a marketing strategy; these are as follows: market size and growth, protection of intellectual property rights, and enforcement of said rights. This report attempts to provide an insight into these criteria as they relate to the Middle East and North Africa market.

Pharmaceuticals market in the MENA

At close to $20 billion, the pharmaceuticals market in the Middle East and North Africa 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 2016, which represents a five-year compound annual growth rate between 2011 and 2016 of over 9 percent. The projected CAGR for developed countries is much lower and declining. The CAGR (2012-2016) in North America ranges between 1 and 4 percent while in Europe, it ranges between 0 and 3 percent.



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, Egypt and Saudi Arabia are the two largest markets. On the other end, the two smallest markets, Bahrain and Oman, have patented drug sales of approximately $0.2 billion and $0.3 billion. These numbers should not come as a surprise since Egypt has the highest population in the region at about 83 million and Saudi Arabia's is just over 25 million. Similarly, both Bahrain and Oman have two of the smallest populations in the region with approximately 1.2 and 3 million.

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 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.

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 or Swiss-type claims are allowed. In some 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.

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The number of MENA countries with PCT membership is increasing, alongside trade agreements between those countries and the US or Europe. These afford prospects for businesses looking to penetrate new markets with growth opportunities.

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. Such is not the case in Saudi Arabia where medical use and Swiss-type claims are allowed, while methods of treatment are not.

The third criterion whose value varies between countries and is of high importance has to do with the legal environment. This criterion includes dealing with the ubiquitous problem of counterfeiting and imitators, such as generic brands. Porous borders, as well as inadequate border control, lead to substantial losses in sales and profits. Patent owners may be resistant to registering and penetrating a market where legal recourse against imitators is ineffective or unavailable. If we were to extrapolate on the evolution of the legal enforcement as it applies to trademarks, it is to be expected that the legal environment surrounding patents will follow suit in providing the adequate protection.

Customs in various MENA countries have become very active when it comes to trademarks. In Saudi Arabia, for example, it has become increasingly difficult for an infringer to import counterfeit goods. Customs check the Trademark Office records if they suspect counterfeit consignments. In 2012, concerted efforts and joint planning by the Commercial Anti-Fraud Department and the Customs Authorities led to a successful year in fighting piracy and suspending a considerable amount of counterfeit imported into the country, including pharmaceutical products.

Other countries have updated their laws to better protect the consumer as well as enable rights holders to take actionable measures. In Egypt, for instance, IP Law no. 82 for the year 2002 introduced new provisions on enforcement against counterfeiting. In these provisions, the judges have the competence to issue provisional measures such as seizure of goods to determine infringement and preserve evidence. With regards to sanctions, this IP law increased the amount of fines and imposed new remedies. Some of these remedies include confiscation and destruction of infringing goods and the tools or equipment used in the infringement. Enforcement in Egypt was taken further by providing an IP unit in the police force, as well as teams of civil inspectors who are authorized to seize infringing goods from the market.

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.

Doing business in MENA countries and sporadic instability may give new players cold feet to enter. Working with a local partner with both local and regional expertise and know-how can alleviate these concerns. With more MENA countries entering into bilateral free trade-type agreements with developed countries, they are more inclined to amend and adopt new laws.

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 untested, seems to be maturing in the right direction.

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MENA: NAVIGATING PHARMACEUTICAL TRADEMARK PROTECTION

Protecting pharmaceutical marks in the Middle East is a challenging, labor-intensive process, which requires special consideration and handling. However, with high imports of branded drugs and soaring growth, this is not a market that rights holders can afford to ignore.

The Arab pharmaceutical market is reportedly worth around $20 billion and estimated to grow at a compounded annual growth rate of about 9% over the five-year period between 2012 and 2016. Around 450 pharmaceutical manufacturers operate in the region. With the exception of Egypt, all Middle Eastern countries are high importers of branded drugs, while local manufacturing capabilities are mostly limited to generic and licensed drugs with very little R&D. For this reason, it has become more and more important for trademark holders to address the challenges of pharmaceutical trademark protection in the Arab world and to become more familiar with the requirements that are specific to this region.

Clearance

In addition to a typical trademark search, a full pharmaceutical trademark availability search should attempt to cover a selection of sources, including the records of local regulatory authorities. However, rights holders should be aware of two limitations. First, there is no pan-Arab marketing authorization. Second, not all records are easily accessible.

Examination

In general terms, trademark offices throughout the region have developed better judgment for assessing the likelihood of consumer confusion between pharmaceutical trademarks. The issue of consumer sophistication with regard to prescription drugs is taken into consideration in some countries, such as the United Arab Emirates, Bahrain and Jordan. Examination on relative grounds is performed by the trademark offices of all Arab countries, except for Morocco and Lebanon.

When it comes to international non-proprietary names (INN), there seem to be no specific regulations to prevent the acquisition of proprietary rights on INNs, including prohibiting registration of the name as a trade name or a trademark. Although the World Health Organization (WHO) has requested that member countries should take the necessary steps to prevent the acquisition of proprietary rights on INNs, including prohibiting registration of the name as a trade name or a trademark, practice across the region varies considerably. In countries where there is no substantive examination, such as Lebanon and Morocco, the registrar will not check whether the trademark is an INN. In other countries where substantive examination exists, the examiners are not expected to verify whether the mark is an INN, but it may be possible to oppose a trademark based on the fact that it is identical to an INN or an INN stem.

Packaging

There are regulatory requirements for pharmaceutical packaging (e.g., the display of ingredients, side effects, and language and safety warnings) in almost all Arab countries. With regard to language, the regulatory requirements in some countries call for the use of the mark in Arabic on the package and/or the leaflet – specifically, in Morocco, Tunisia, Egypt, the United Arab Emirates, Syria, Saudi Arabia and Qatar. Hence, protection of the mark in the Arabic script is necessary in countries where use in Arabic is required, although the registration of a trademark in English should, in general, provide protection against the registration of another mark with a prominently featured or at least confusingly similar Arabic transliteration that could cause public confusion.

Requirements

No countries in the Arab region impose filing requirements that are specific only to Class 5, except for Syria. The Syrian Trademark Office asks for detailed information on the origin of the product in support of the trademark application.

Legalization of supporting documents is required in all territories, except for Algeria, Morocco, and Gaza. Use is not a requirement for registration in all countries. The same is also true for renewals, except for Algeria. However, failure to use the trademark within a specified period will make a registration vulnerable to cancellation by any interested party on the grounds of non-use.

Enforcement

According to the WHO, the incidence of counterfeit drugs in emerging countries is up by between 20% and 30% of the market. The distribution channels in these regions are less strictly controlled and it is more difficult to prevent counterfeiters from infiltrating supply networks.

In many countries of the Arab world, counterfeiting in general, and especially the counterfeiting of medicines, is not a criminal offence. When it is, penalties are usually not specific to counterfeit medicines, but common to all cases of counterfeiting, especially the infringement of IP rights. Penalties vary from country to country and may include fines, imprisonment and the confiscation and destruction of counterfeit goods.

A number of strategies can be implemented on the enforcement front across Arab countries, using a wide range of methods, from site investigations and raids to civil and criminal legal actions, as well as customs seizures. Another key tool for maintaining an effective enforcement strategy is through the customs recordal procedure, which has been adopted in Algeria, Morocco, Sudan, Tunisia and the United Arab Emirates. Recordal is also expected to be adopted in Qatar and Abu Dhabi (a UAE emirate), but the timing for implementation is unknown. One fundamental premise of the recordation system (other than providing a central registry containing information for recorded trademarks) is that it allows customs officials to adopt an *ex officio* border system. This differs from the standard border system, in which a judicial authority orders Customs to detain the infringing shipment after identifying the infringing goods. The key advantage of the *ex officio* system is that it allows for prompt and proactive action by customs officials, thus avoiding the delays inherent in seeking judicial action. Customs officials are always on the lookout for infringing goods and are thus able to act quickly to confiscate counterfeit and pirated merchandise. In short, rights holders must be ready and willing to adopt a model that incorporates both legal and regulatory approaches in order to arrive at a well-established trademark protection strategy.

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