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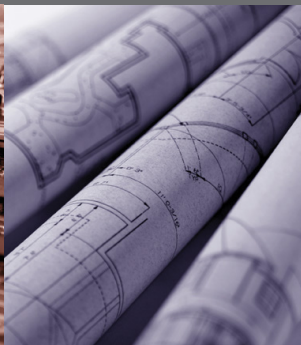
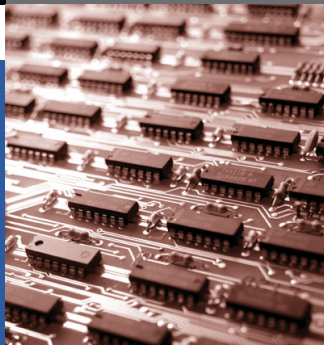


# SABA

A Review of Intellectual Property-Related News and  
Developments in the Middle East and North Africa

# IP BULLETIN

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## Arab World: *Opportunities and Risks for Pharma*



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 article 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 1-4 percent while in

Europe, it ranges between 0-3 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.

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 pat-



## Arab World: Opportunities and Risks for Pharma

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ent 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 which 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 counterfeits 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 lo-

cal and regional expertise and know-how can alleviate these concerns. With more MENA countries entering into bilateral free trade-type agreements with developed countries, the more inclined they are 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.

## Djibouti: *Small Country, Big Ambitions*



With an area of 23,200 square kilometers, it is easy to overlook Djibouti on a map. This small country, however, occupies an unrivaled regional role that is increasing in significance. As the largest deepwater port off of the coast of the Red Sea, Djibouti serves as an international refueling and transshipment center. It also offers a route to the sea for Ethiopia and South Sudan.

Imports and exports, to and from Ethiopia mainly, account for most of Djibouti's harbor traffic. Transportation and warehousing costs are inflated, which leads to the occasional auctioning of goods into the Djiboutian market. This is because imports remain in Djibouti for a period of time ranging between three to six months before being released.

Djibouti experiences stable economic development as the annual GDP growth averaged 5 percent due to good performance in the services sector. The GDP is \$2.505 billion, while the

GDP per capita is \$2,700. The GDP composition is 3 percent for agriculture, 17.3 percent for industry, and 79.7 percent for services.

The country encourages foreign investment. With laws based on the French legal system catering to the benefit of investors, the Djiboutian investment code guarantees investors to freely import all the required material for their investments. The Djiboutian law protects the acquisition and disposition of all property rights, intellectual property, patents, copyrights, trademarks, and trade secrets.

In addition to being a signatory to TRIPS Agreement and a member of the World Trade Organization, Djibouti observes the WIPO Convention, the Paris Convention, and the Berne Convention. Djibouti has passed a law enforcing the protection of copyrights and maintains an Office of Industrial and Commercial Property Rights for the protection of

property rights.

Trademarks are registered in Djibouti, in accordance with the 8th edition of the Nice International Classification, for a period of 10 years from filing date and are renewable for like periods. A grace period of six months is observed. A single application can include several classes. Provisions apply for the registration of collective marks and certification marks. Examination on relative grounds is not performed.

The main features of trademark registration are as follows:

- Trademark applications and registrations may be assigned with or without the goodwill of the business concerned
  - A change of name/address can be recorded for trademark applications and registrations
  - License recordal is compulsory in order to be effective against third parties
  - A merger may be recorded for trademark applications and registrations
  - Marking is not compulsory
  - A registered mark can be cancelled by the decision of the Court at any time if the conditions of grant were not respected
  - The time frame for completing the registration process is 10 to 12 months
- Protection of patents and industrial designs is based on the implement-

ing regulations of Industrial Property Law no. 50/AN/09/6ème which came into force in Djibouti on November 25, 2011, Decree No. 2011-079.

The main features of the patents and industrial designs protection framework are as follows:

- Patents may be granted with respect to products and processes, as well as new applications or combinations of known means to arrive at new results
- Inventions must satisfy the criteria of novelty, inventive step and industrial applicability
- Exclusions from patentability are methods of diagnosis, therapy and surgery for the treatment of persons or animals
- Patents will be granted for 20 years from filing date
- Maintenance fees are payable for consecutive periods of 5 years from the date of filing. There is a grace period of six months
- A single industrial design application may contain up to 100 models or designs, as long as these are intended to be incorporated in objects grouped in the same class of the Locarno classification system
- Industrial designs will be registered for an initial period of 5 years from the filing date, renewable for a further two consecutive periods of 5 years upon the payment of renewal fees, with a grace period of six months.

# IP HIGHLIGHTS

## South Sudan: *Time to Register Your Marks*



Following the separation of South Sudan from Sudan in 2011, authorities are now expected to issue a new trademark law that would be in compliance with the international standards. However, the enactment of the new law is not presumed to take place

in the near future. In the meantime, the Ministry of Justice is now admitting trademark applications under the provisions of the trademarks act of 1969 that is currently in force in the neighboring Sudan.

In principle, registrations, submitted under the act of 1969, will remain valid after the issuance of the new trademark law of South Sudan. Saba & Co. IP will monitor the situation and provide updates should any changes occur

## Saudi Arabia: *Establishment of Commercial Arbitration Center*



Arbitration has become more efficient in resolving conflicts in the Kingdom of Saudi Arabia after the establishment of the first Commercial Arbitration Center.

Walkthrough of the Saudi Commercial Arbitration Center:

- The Center's head office location is in Riyadh, but the Council of Ministers seeks establishing branches in other parts of the Kingdom
- The Council of Chambers of Commerce and Industry directors will run the center
- The Ministry of Justice will handle the issuance of licenses for the center
- The directors will regulate the arbitration and incurring fees and expenses
- The concerned ministries will also provide arbitral aids funded by the government to those involved with claims

## Regional News in Brief:

### Yemen:

The Yemeni government has significantly increased the official publication fees of trademark, patent and industrial design applications by virtue of Ministerial decision no. 105/2014 (issued on July 1, 2014), while all other fees remain the same.

The new rates will be applicable on all applications filed on or after August 7, 2014. For your information, trademark, patent and industrial design applications are published in the Official Gazette upon acceptance. Oppositions may be filed within 90 days from publication date.

### Tunisia:

Following in the footsteps of its neighbor Morocco, the Tunisian patent office, or the National Standardization and Industrial Property Institute, signed, on July 3 2014, an agreement which will allow owners of EPO grants to validate their patent(s) in Tunisia by designating it as they would any other EPC member state. Although neither country is an EPC member state, these agreements will give both countries a pseudo-EPC status with regards to patent protection, and will encourage more filings and foreign investment.

Neither country's respective patent office currently performs substantive examination. Thus by entering into this type of agreement with the EPO, both countries have ensured that validated patents in their countries will have the same legal effect as national applications and patents, and will be subject only to local patent legislation.

As a reminder, in December 2010, the Moroccan patent office, or the Moroccan Industrial and Commercial Property Office (OMPIC), signed a similar agreement. Up to this date however, the Moroccan patent law has not been amended to start implementing the validation of European grants. It is anticipated that such an amendment will be introduced this year and voted into law.



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