

**SABA**  
INTELLECTUAL  
PROPERTY

**BULLETIN**

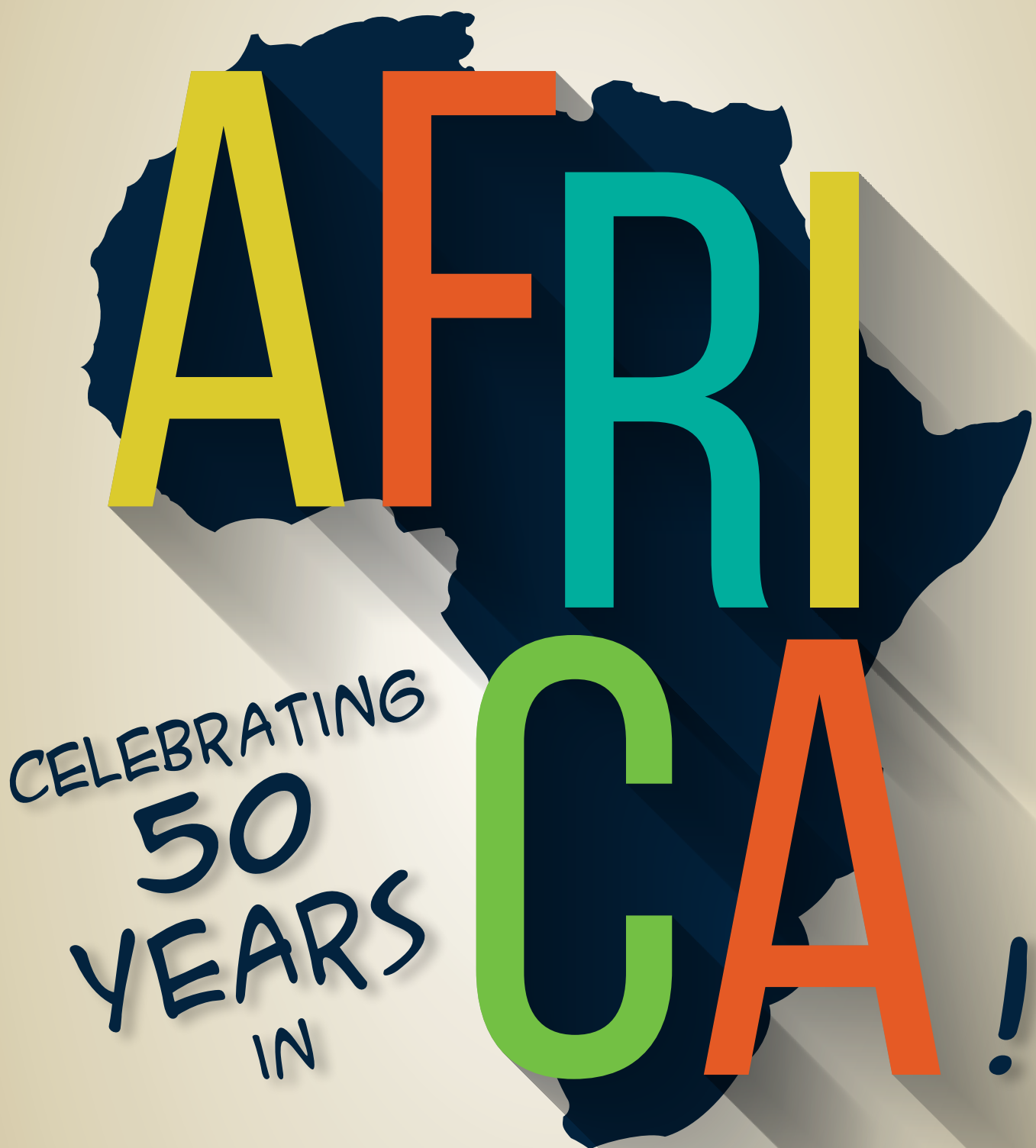
March 2020

**KUWAIT**  
New Guidelines for  
Pharmaceutical Registration


**WEST BANK**  
Procedural Change  
for Trademark Registration

**MENA**  
Back to the Future, Patent Term  
Extention in the Region

WITH THE WIDESPREAD OF  
CORONAVIRUS (COVID-19), **WE WANT**  
**TO SEND OUR BEST WISHES FOR**  
**EVERYONE'S SAFETY.**



## KUWAIT | NEW REGULATIONS FOR PHARMACEUTICAL REGISTRATION



**Following the issuance of Ministerial Decree no. 361 of 2019 that was published on January 5, 2020, the Ministry of Health (MOH) in Kuwait updated the regulations regarding the registration of pharmaceutical products.**

In line with local legislation, pharmaceutical products must be registered with the MOH before being imported into the Kuwaiti market by local agents. The local agents should in turn be licensed by the Ministry of Commerce and the MOH to import and distribute such products.

In order to apply for marketing authorization, a common technical document must be submitted to the MOH for assessment and approval. It is worth noting that registration is allowed for biological products and biosimilars, which must satisfy the technical and product class specific provisions set out in the Gulf Health Council guidelines and must be registered with a competent authority, such as the United States Food and Drug Administration or the European Medicines Agency.

The Decree lists, among other things, the requirements for registration of marketing authorization holders with the MOH and bilingual (Arabic and English) product labelling. Registration certifications are valid for five years from the date of issuance and renewal files must be submitted six months prior to pharmaceutical registration certificate expiry.

With regard to language, the regulatory requirements in Kuwait call for the use of the mark in Arabic on the package and/or the leaflet. Hence, protection of the mark in the Arabic script is recommended, although the registration of a trademark in Latin 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.

## WEST BANK | PROCEDURAL CHANGE FOR TRADEMARK REGISTRATION



**The Trademark Office in West Bank announced that a scanned copy of the power of attorney must be submitted at the time of filing, and the legalized POA may be submitted within three months from the filing date.**

The outgoing procedure did not require submitting a copy of the POA at the time of filing.

It is worth noting that the TMO will not accept any POAs that are 10 years and older for filing new trademarks applications as of July 1, 2020.

### **TRADEMARK PROTECTION FRAMEWORK IN WEST BANK**

#### ***Classification***

10th edition – single class application

#### ***Search***

Possible for word and device marks

#### ***Examination***

On formal, absolute, and relative grounds

#### ***Opposition***

3 months from publication date

#### ***Protection Term***

7 years from filing date and renewable for periods of 14 years each

#### ***Use***

Vulnerable to cancellation if mark has not been used for 5 years from registration date

**MENA | BACK TO THE FUTURE, PATENT TERM EXTENSION IN THE REGION**

**Patent Term Extension (PTE), also known as Supplemental Patent Certificate (SPC) in some countries, is a mechanism by which patent owners may request an extension on the life of a patent. In most countries where such a practice is applicable, PTE or SPC is generally and primarily used by pharmaceuticals and biotechnology companies, but depending on the provisions in the laws, other industries may also benefit from these extensions.**

Patents generally provide for a protection period of twenty years, calculated from the first claimed priority, the national or international (PCT) filing date. The base date varies depending on the patent filing route chosen as well as the national laws and regulations. With only a few exceptions, twenty years is the expected and anticipated norm.

As most countries apply the first-to-file principle on rights to an invention, companies and individuals working in highly competitive industries find it necessary to secure the earliest filing date possible by doing a first patent filing as soon as an idea is elaborated enough to be considered a commercially viable invention, and even sometimes earlier. This means that a patent application may undergo prosecution and examination and possibly be granted and issued long before the product or process of the invention has been fully developed and ready for commercialization. It may then be ten to twelve years from that first filing date before the invention is ready to be used commercially, thus effectively giving the patent owner only eight years of exclusive rights.

The delays in taking an invention to market may not be due to the owner. These may result from regulatory delays. In such cases, a number of patent systems have accounted for this unintentional delay by allowing the patent owner to request an extension of time on the expiration term of a patent, for at least the period of the delay incurred by the regulatory authority.

In certain patent systems, the delay in granting a patent as a



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result of delays in the overall prosecution by the patent office enables the patent owner to request an extension as well. This type of extension is calculated from either the filing date or start of examination date, and again for at least the period of the delay incurred by the patent authority. Generally speaking, most systems that deliver such a PTE place a cap on the extension term, for example, no more than two and a half years.

**This brings us to the existing systems in the countries of the Middle East and North Africa (MENA) region. The countries where a patent owner is eligible to request a patent term extension pursuant to the provision in the laws are: Bahrain, Jordan, Morocco and Oman.**

Bahrain and Oman's patent laws provision for the same conditions for requesting a PTE. The implementing regulations relating to these provisions are however not clear. According to the latest issued regulations in Bahrain, these are silent on the guidelines or procedures enabling a patent owner to request and obtain a PTE.

Pursuant to the laws of these two countries, a patent owner may request a PTE under both circumstances described above. In the first scenario, a patent owner may request compensation for the unreasonable delay in granting the patent for reasons beyond their control. In the event a patent is granted more than four years after the filing date, or two years from the request for examination, whichever is later, and for reasons outside the applicant's control, the term of protection of that patent shall be extended so as to compensate for said delay. Whereas in Bahrain the law does not specify the maximum extension period, in Oman, the extension shall not exceed five years from the normal expiry date.

In further provisions in the Bahraini and Omani laws, an adjustment of the patent term shall be available if the marketing approval process related to the first commercial use of the product is delayed due to actions not attributable to the patent owner.

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Here again, the Bahraini law is silent on what is considered a delay, whereas the Omani law defines the delay as being in excess of twenty four months from the date of application of marketing approval.

A point to consider with regards to these two countries: PTE can only be requested for national patents. As a reminder, patent protection is extended into Bahrain and Oman via the regional GCC patent system. An extension may not be requested or applied to a regional GCC patent in either country.

**As a result, a number of filers in the region have opted to extend patent protection to the GCC countries via national stage PCT filings instead of the GCC route, in order to benefit from specific national laws and regulations.**

In Morocco, a patent owner may request a PTE in the latter case only and the same is only applicable to pharmaceutical products. The duration is equal to the number of days between the expiration date of the deadline for granting a marketing authorization and the effective date of its deliverance. The law further specifies that a patent owner has to file a PTE request within three months from receiving a marketing authorization. No such deadline is recited in the Bahraini and Omani laws. In the case of Morocco, the law stipulates that the PTE cannot extend beyond two and half years.

As for Jordan, the provisions are unique for the region. A request to obtain a PTE should show evidence that there was unreasonable curtailment of the patent term as a result of the marketing approval process; essentially, the date of submitting the marketing approval and the date of marketing approval. Such a request must be submitted within six months from the date of obtaining the first marketing approval worldwide or in the country of origin. The PTE cannot extend beyond five years from the expected expiration date.

In the absence of specific regulations and/or guidelines in the provisions relating to PTE, there does not appear to be restrictions

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on the type of patents that qualify for extension. In particular, for pharmaceutical patents, a PTE may be requested for small molecules, biologics, second medical use, formulations, and others. The number of PTE requests and grants are relatively small and possibly not adequately taken advantage of in the region. As a result, there is little experience to challenge the boundaries and exceptions which may be applicable.

With the steady growth in foreign patent filings in the MENA region as a whole and the four countries presented in this piece, it is critical for patent applicants and owners to better understand their options in order to develop their strategy. Budgets may limit the ability of pursuing a very broad filing strategy. It becomes necessary then to evaluate the pros and cons of patenting in specific markets and to assess, amongst other things, the additional benefits from obtaining a patent in specific countries.

As a developing region, information such as PTE in the countries of the MENA is not necessarily readily available. Factors that contribute to choosing a country for filing patents extend beyond the availability of a patent system and adequate enforcement. Provisions on filing divisional applications or patents of addition may be of importance to certain applicants. To others, the availability of a patent listing or patent linkage system may be an important criterion. Choosing the right local IP associate can make the difference in securing a successful and useful patent portfolio in the region.



IT'S NOT ABOUT  
BEING THERE.  
IT'S ABOUT  
BEING AWARE.



"THE OTHER  
FIELD"  
EDWARD HOPPER 1966

**90<sup>+</sup>**

YEARS OF EXPERIENCE

**18**

OFFICES

**1**

STOP SHOP IP FIRM

COUNSELING | PROSECUTION | ENFORCEMENT | ANTI-COUNTERFEITING

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