



**ASSESSMENT OF NATIONAL INTELLECTUAL PROPERTY LANDSCAPES
AND THEIR IMPACT ON ACCESS TO MEDICINES
(EGYPT, MOROCCO, TUNISIA)**

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Cover photography courtesy of Lionel JOUVE.



Title: A tool to assess how friendly to access-to-medicines your law is Background

Provisions of intellectual property (IP) may have an important impact on access to medicines. For instance, the monopoly granted by the patent prevents competition with generics on the market and is often responsible for high prices. Along the years, IP provisions grow more numerous and complex in legal documents. Policy makers, public health experts and NGOs involved in access to medicines need to be able to understand these provisions.

Objectives:

A study was undertaken to assess provisions on intellectual property in different bodies of laws (patent laws, pharmaceutical regulations, decrees on pharmaceutical products, free trade agreements, etc.) prone to have an impact on access to medicines in three countries: Egypt, Morocco, and Tunisia.

Methods:

Each of the relevant provisions was described, analyzed, and was assigned a score. Scores are estimations drawn up by the researcher based on her assessment of the impact of the provisions either as barriers or playing a facilitating role to access to medicines. They are a subjective assessment and not meant to provide a strict ranking for each country, however, they give a sense of the level of flexibilities available within the laws of the different countries in order to ensure access to medicines, and allow comparisons between countries.

The categories of provisions considered include:

- Extension of patentability;
- Procedure to oppose a patent;
- Extension of duration of patent monopoly;
- Limitations to the use of compulsory licenses;
- Parallel import of medicines;
- Data exclusivity in the context of the marketing authorization process;
- Linkage between the patent status and the marketing authorization;
- Experimental use of patents and Bolar provision.

Results:

The results are presented through tables. The situation of each country can be compared for each time of provision to the situation in the two others. The provisions that are the more useful to access to medicines, or, on the contrary, the detrimental were identified in the three countries. These results constitute a resource to help people understand and improve the legal framework around medicines in their country.

Conclusions and Recommendations:

The methodology developed is meant to serve as a tool for policy-makers, public health experts and NGOs to assess the IP landscape and its impact on access to medicines in their country and compare it to others. This tool was designed to be discussed and shared by its users in order to assess the situation in an increasing number of countries.

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OBJECTIVES AND METHODOLOGY OF THE STUDY

This study is based on a qualitative analysis of provisions that might have an impact on access to intellectual property in different bodies of laws in the three countries (patent laws, pharmaceutical regulations, decrees on pharmaceutical products, free trade agreements, etc.). These provisions are described and analyzed, and a score is assigned to each one so as to compare the different situations between the countries. Scores are estimations drawn up by the researcher based on her assessment of the impact of the provisions either as barriers or playing a facilitating role to access to medicines. They are a subjective assessment and not meant to provide a strict ranking for each country; however, they give a sense of the level of flexibilities within the laws of the different countries in ensuring access to medicines.

The categories of provisions considered are limited. They include:

- Extension of patentability;
- Participation of the health ministry in the granting of patents on pharmaceuticals;
- Opposition and pre-grant opposition to a patent;
- Extension of duration of monopoly in relation to patent granting;
- Extension of duration of monopoly in relation to marketing authorization;
- Grounds and limitations for the use of compulsory licenses;
- Parallel import;
- Data exclusivity;
- Experimental use and Bolar provision;
- Others types of provisions that can have an impact.

Provisions are given a positive score (+1, +2, +3) when they have a positive impact on access to medicines and a negative one when they can hamper it (-1, -2, -3). Three is the highest possible score in the study.

Some provisions are considered to be more useful or essential, or on the contrary more detrimental than others. A provision on compulsory license that is issued on very restrictive grounds and a provision on linkage have both negative effects, but the former can impose more definitive limitations than the latter. Score of +/-0.5 are usually for elements of provisions that tend to complicate the use of a flexibility or, on the contrary, mitigate a provision that can impact negatively access to medicines.

The exclusion of a flexibility that is included in the TRIPS agreement necessarily scores negative. However, the absence of a provision that can improve access though not mentioned in the TRIPS agreement (for instance, the participation of the health minister in the process to review a patent application) scores 0.

The results presented in this study only concern the body of laws that are mentioned (cf. list) and existed when the study was conducted. Some of them did not have an impact on the medicines insofar as intellectual property rules are concerned, which is mentioned in the table. Provisions that are part of free trade agreements still under negotiations or that are not implemented are not taken into account in the final score.

This methodology is meant to serve as a tool for policy-makers, citizens and NGOs to assess the intellectual property landscape in their country and compare it to others. A tool designed to be criticized, discussed, and improved upon.





MOROCCO

MOROCCO

In 2004, a new intellectual property law was adopted in Morocco to comply with the standards required by the World Trade Organization (WTO).¹ The new legislation, 17-97, was implemented on December 18, 2004, amending and reforming pre-existing provisions.² It includes levels of protection of intellectual property rights at least as high as those of the TRIPS agreement. In March 2006, the law 31-05 was promulgated amending law 17-97 to introduce some of the requirements of the free trade agreement concluded with the United States in March 2004 and provisions from WIPO treaties ratified by Morocco. Eight years later, a new law on industrial property (23-13) was adopted. It includes several generations of restrictions that exceed WTO requirements and the standards of the TRIPS agreement, either by expanding and strengthening intellectual property protections or by undermining existing flexibilities left to overcome or bypass these protections when necessary. However, some provisions were also introduced to mitigate these TRIPS+ protections.

Extension of patentability

The Moroccan law (23-13) uses the TRIPS agreement definition of what constitutes an invention and fulfills the criteria of patentability (art. 22, art. 26 and art. 28): it must be a “new invention”, i.e. “not included in the state of the art”, representing “an inventive step” and capable of a possible “industrial application”. Following WTO requirements, in 2004 the Law 17-97 introduced the patentability of pharmaceutical products, in addition to the patentability of production processes, as well as the protection of combinations or pharmaceutical compositions (art. 21)³. Following the signature of the FTA with the US, the article 21 also authorizes the granting of a patent on “new[s] application[s]” and does not exclude the possibility to deliver patents for new uses of an already patented product – which may lead to the protection of all sorts of minor changes of already known substances and the prolongation of the monopoly beyond the initial 20 years of patent protection.⁴ This establishes very low criteria of patentability which facilitate the granting of questionable and unwarranted patents.

On the other hand, the new law excludes the patentability of methods of surgical or therapeutic treatment, as well diagnostic methods (art. 24) as provided for by article 27.2 of the TRIPS Agreement. This was unchanged by the trade agreement with the US – contrary to other FTAs with the US in which it was required. Article 25 however nullify the possibility of excluding plants and animal from patentability in many circumstances: if biological material is isolated from the plant or the animal, if the technical feasibility of the invention is not limited to a vegetal variety or animal race, and if the plant is not covered by a plant variety certificate.

Pre-grant opposition to patent

Article 14.3 of Law 23-13 introduces the possibility of observations from a third party during the patent grating process, however the Moroccan legislation does not include the possibility to oppose a patent before it is granted (“pre-grant opposition”). The party requesting the patent has 2 months to respond to the observation if he decides to do it. It is then for the patent office to decide to grant the patent or not; there is no obligation to take the observations into account (art. 43.2).

1- According to article 65.2 of the TRIPS agreement, Morocco, like other “developing” countries, did not have to apply most of the provisions of the TRIPS Agreement until 1 January 2000. Like many countries at that time, Morocco did not protect pharmaceutical products per se by patent but, prior to January 1, 1995, only applied patent protection to fabrication processes. Following article 65.4 of the TRIPS agreement, such countries had up to 10 years after the entry into force of the TRIPS agreement to introduce patent protection on products. In Morocco new legislation was passed in 2000 to comply with the TRIPS agreement. However, the legislation was not implemented until December 18, 2004. Contrary to many countries, Morocco made full use of the extended deadline for TRIPS compliance.

2- Two legislations governed intellectual property in Morocco during the pre-TRIPS era: one from June 23, 1916 that covered the former French area and was amended in 1941 and one from October 4, 1938 that applied in the former international area of Tangiers.

3- In the case of Morocco, these TRIPS-plus provisions included in the implementation of the TRIPS agreement do not seem to be US requirements but are the result of technical assistance from European countries.

4- The patentability of “new uses or methods of using a known product, including new uses of a known product for the treatment of humans and animals” is stipulated by article 15.9.2 of the FTA with the US.



Articles 85 and 86 provide the possibility of actions to invalidate a patent once it is granted: it is a court that will make the decision upon request from any interested party.

A pre-grant opposition procedure was introduced in the Moroccan law for trademarks on February 20, 2006 and is now described in articles 148.2 to 148.5 of Law 23-13. Following the example of other countries (Egypt, India, Brazil, etc.), Morocco could decide that it represents a useful provision for patents as well, but it would have to cope with the fact that it is forbidden by the FTA with the US (art. 15.9.5). Furthermore, the FTA restricts the grounds for revocation of a patent to the reasons that should have prevented it from being granted in the first place, such as “fraud, misrepresentation or inequitable conduct” (art. 15.9.5); grounds for revocation under the TRIPS agreement, such as the absence of local production, the absence of exploitation of the patent, or reasons of public health are excluded.

Extension of the duration of the patent protection

The Law 23-13 includes the possibility (introduced in 2006 with Law 31-05) to extend the duration of the patent protection (Article 17.1) “if a patent is granted after a period of four years from the filing date of the patent application”.⁵ This requirement corresponds to one of the provisions of the free trade agreement signed with the United States.⁶ The lengthening of the patent protection is equal to the number of days from the first day after the period of four years until the effective date of the granting of the patent.

The duration of the protection can also be extended beyond the initial 20 years “of a duration equal to the number of days past between the date of expiration of the delay given to grant a marketing authorization and the effective date of its granting”⁷ (art. 17.2) (also introduced already in 2006 with Law 31-05). However, the extension can only be granted once for a given product and that it cannot exceed two and a half years (art. 17.3), while the request for extension must be made within 3 months after the granting of the marketing authorization (art 17.2). This extension is called a “certificate”.

Both extensions were required by the FTA signed with the US.⁸ However, several provisions were introduced by Law 23-13 in order to mitigate their effect. The certificate of extension can only be granted if the product is covered by a patent, if there is a valid marketing authorization, and if it is the first time this product gets a marketing authorization and no certificate has already been granted for it. The certificate can only cover the product benefiting from the marketing authorization (art. 17.4). The certificate has no effect if the owner renounces it, if the owner did not pay the fees required, or if the product is not more authorized on the market (art. 17.5). The certificate is void if the owner did not pay the fees required or if the patent is cancelled or limited so that the product is no more protected by the monopoly rights given by the patent (art. 17.6). Thus article 17.6 should allow to lift the protection from the certificate in case of compulsory license.

Limitation on compulsory licensing

Regarding compulsory licensing, the Moroccan legislation contains a series of elements that restrict its use. These restrictions are not new and were already present in the law at the end of the 1990s. Compulsory licensing may be requested only 3 years after the granting of a patent or 4 years after filing of the application. On one hand, this requirement of the Paris convention applies to compulsory licensing granted on the ground of “failure to work or insufficient working” (Art. 5.A(4)). The TRIPS agreement, on the other hand, leaves states free to decide of the reasons why they want to use compulsory licensing, as the Doha declaration from the WTO reminded in 2001: “Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted” (§5.b). In its article 60, the Moroccan law limits the grounds

5- Translation by the author.

6- The FTA requires that patent extensions be granted to “compensate for unreasonable delays that occur in granting the patent” (art. 15.9.7).

7- Translation by the author.

8- The FTA requires that patent extensions be granted to compensate for “unreasonable curtailment of the effective patent term as a result of the marketing approval process” of pharmaceutical products (art. 15.10.3).

of compulsory licensing to cases where: the patent owner is not exploiting the invention, or the product has not been commercialized in sufficient quantity for the national market, or the patent owner has not exploited the patent or marketed the corresponding product for at least three years. Beside failure to work the patent or insufficient working of the patent, there are no grounds for compulsory licensing based on the public interest.⁹ In line with requirements of the article 31 of the TRIPS agreement, compulsory licenses can only be granted after an attempt to negotiate with the patent owner and if the party requesting the license can prove ability to fulfill domestic needs (art. 61), it is non-exclusive (art. 62), in line with requirements of the article 31 of the TRIPS agreement on compulsory licensing. They can only be granted by a court that establishes the conditions of the license, its duration and sets the appropriate royalties (art. 62 & 63).

If the general provision for compulsory licensing is limited, there is, however, the option of a “licences d’office” (ex officio licence) in the “interest of public health”. It can be granted for pharmaceutical products through an administrative act, at the request of the administration in charge of public health (art. 67). This provision can apply when medicines are not available in “sufficient quantity or quality” on the market or because the price is “abnormally high”. No prior negotiation with the right holder is required. This provision can be used in order to export medicines to countries that have no or insufficient production capacities (this was added in the law following the agreement at the WTO on export of medicines produced under compulsory licensing in 2003).

A decree passed in June 2004 to implement the law 17-97 established the administrative procedure to review and grant ex officio licenses¹⁰. According to this decree, the governmental authority in charge of health sends any request for an ex officio license to the authority in charge of industry and commerce. The latter notify the rights owner of a request for exploitation. The rights owner is given 15 days to react and send observations. After this period, the authority in charge of industry and commerce submits the request to a technical commission.¹¹ The commission has to provide an opinion within 2 months after the request has been made. The exploitation of the patent is enacted by decree in response to a proposition from the authority in charge of industry and commerce and a request by the governmental authority in charge of health. Request for exploitation from third parties are to be addressed to the authority in charge of industry and commerce and the authority in charge of health. A license can be granted to them by decree in response to a joint proposition from the authority in charge of health and the authority in charge of industry and commerce. The fact that there is a deadline for this commission to render its opinion is a positive element because it prevents unlimited delays. However, the procedure involves many different bodies and a succession of steps that can make the procedure a long and arduous one. Besides, there is no time limit regarding the emission of the decree by the governmental authorities. The Moroccan law also stipulates that ex officio licenses can be granted to meet “national economic needs” or “national defense needs” (section II of the June 2004 decree). However, contrary to the TRIPs Agreement, the language of the law does not include “situations of national emergency”, “cases of public non-commercial use”, or the need to “remedy a practice determined after judicial or administrative process to be anti-competitive”; and as a consequence the grounds for issuing a license are more limited than in the TRIPS agreement.

The code for medicines, as modified in 2006 (Law n°17-04), states that the marketing of a generic version of a medicine can only take place once the patent protection is over (art. 16, paragraph 4). This obligation required by the US FTA prevents the efficient use of compulsory licensing by banning the marketing of a generic version of a drug legally produced and/or imported under compulsory licensing.

Another provision of the same law could be used to override this limitation (art. 16 paragraph 1 & 2): it states that despite all provisions establishing protections on pharmaceutical speciality, the administration is allowed to take all necessary measures to facilitate access to health. However, it is limited to cases of severe epidemic,

9- Article 71, 72 and 73 state that an administrative decree can decide of the use of a patent by a third party if after one year the patent holder noticed formally to satisfy the needs of the domestic economy are still not exploiting the patent or are exploiting it in insufficient quality of quantity to the detriment of the economic development and to public interest. However, this is very narrow ground for the use of that sort of compulsory license.

10- Modifications were introduced in the decree n° 2-05-1485 of February 12, 2006.

11- The composition and the functioning of this commission are to be defined by a joint decree from the authority in charge of industry and commerce and the commission on health.

cases of extreme urgency or cases of national disaster and to situations where a pharmaceutical speciality is “provided to the public in insufficient quantity or quality or at an abnormally high price.”¹²

Limitation of parallel import

Parallel import allows nationals to buy a patented good from outside of their country, for instance patented medicines that are sold at a cheaper price abroad. A parallel importation is an importation of a patented product without the consent of the patent-holder. Parallel import is based on the legal notion of “exhaustion of rights” according to which a right owner is correctly and definitively remunerated once the product is put on a market. As the right owner has exhausted his/her intellectual property rights on the commercial exploitation of the good through the act of selling the product, s/he cannot prevent the circulation of patented goods put lawfully on the market. The regime of exhaustion of rights can be international, regional or national. The principle of national exhaustion of rights means that the right owner, once he has put the product on the national market, loses control on how it is resold on this market. However, s/he (or somebody s/he has authorized) can oppose importation of patented product from abroad. In case of international exhaustion of right, once the product is put on the market somewhere in world, the patent holder loses the authority to prevent parallel importation – that is importation from any place in the world.

Article 6 of the TRIPS Agreement explicitly states that practices relating to parallel importation cannot be challenged under the WTO dispute settlement system. The Doha Declaration has reaffirmed that Members have this right, stating that each Member is free to establish its own regime (international, regional or national) for such exhaustion without challenge. However, article 55.e of the Law 23-13 sets a regime of national exhaustion of right and therefore prevents parallel import. This limitation was requested by the US FTA, but was already in the law in 2004.

Data exclusivity

With the US FTA, Morocco agreed to introduce into its legislation additional ways to create exclusive rights and monopolies. The FTA imposed exclusive rights on the data required for the registration of a medicine for a minimum of 5 years: “If [the] Party requires, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of: (a) safety and efficacy data, or (b) evidence of prior approval of the product in another territory that requires such information” (art. 15.10.1).

To obtain marketing approval for a new product, pharmaceutical companies must submit data proving the absence of toxicity and the effectiveness of the product to drug regulation authorities. Such data are referred to as “registration data” or “marketing approval data” and result from tests and clinical trials on animals and human beings. When a company wants to market a generic version of a pharmaceutical product already on the market, the regulatory authorities do not ask it to undertake the same clinical trials (which would be unethical); they ask the company to provide the results of bioequivalent tests proving that the product is chemically equivalent and has the same action in the human body as the brand-name product (bioequivalent). The authorities rely on the data on toxicity and effectiveness provided for the marketing of the first product to be registered. Data exclusivity establishes a marketing monopoly as it prevents competitors from marketing their product unless they conduct new clinical trials.

Moreover, this provision can render useless the granting of compulsory licensing to allow access to generic versions of patented products: even if a license is issued and the drug is produced or imported, it will not be able to enter the market. Even old products, unpatented products can benefit from a monopoly under this provision, as long as they have not already been marketed in Morocco.

In the case of a product already on the market in Morocco, the FTA with the US introduced the possibility to obtain an exclusivity for three years (art. 15.10.2). Thus, on the basis of “new clinical information” provided for a

¹²- Translation by the author.

new therapeutic use, it allows unlimited renewal of exclusive rights by permitting an additional data exclusivity period to cover the not-yet-approved use of already marketed products.

The implementation of the FTA led to the adoption of a decree on the marketing of pharmaceutical products (n°2-14-841) that established an exclusivity for 5 years of the data submitted when requesting a marketing approval of a new chemical entity and proscribes the marketing of generic versions of the product based on these data (art. 4).

Here also, the article 16 paragraphs 1 & 2 could be an option to override this provision, in cases of severe epidemic, cases of extreme urgency or cases of national disaster, when a pharmaceutical speciality is “provided to the public in insufficient quantity or quality or at an abnormally high price.”

Linkage between patent and marketing authorization

The US FTA established a link between the granting of marketing approval and patent protection (art. 15.10.4). It required regulatory authorities to prevent third parties from granting marketing approvals for products protected by a patent, and to inform patent holders of the identity of third parties applying for marketing approvals during the patent term.

The code for medicines, as modified in 2006 (Law n°17-04), implemented part of this requirement when stating that the marketing of a generic version of a medicine could only take place once the patent protection is over (art. 16 paragraph 4).

Experimental use – Bolar provision

The “Bolar” provision, a provision that can be found in intellectual property laws, including in the US, states that despite the existence of a patent covering an invention, third parties are allowed to work on it during the duration of the patent protection, without the agreement of the right owner. Among other things, it offers the possibility to generic manufacturers to prepare their product and conduct all the tests required by the regulatory authorities in order to obtain marketing authorization faster once the patent has expired.

Since law 17-97, the law on the protection of industrial property mentions in its article 55 of law 31-05 mentions that rights conferred by patents do not apply to experimental acts using the invention. With its last version, law 23-23, it now also states that are also not covered by patent protection “analysis and trials for the obtention of marketing authorization of a medicines, as well as acts necessary to the making of these analysis and trials and for the obtention of the authorization” (paragraph d).

A disposition has also been added to the new pharmacy code in article 16: it allows an industrial pharmaceutical facility wishing to market a generic product to undertake any necessary trial or experimentation on the proprietary product before expiration of the patent.



Scoring

Table 1: Scoring for Morocco

Extension of patentability	Patentability of new uses	-1
	Patentability of combinations	-1
	Not patentable methods of therapeutic or surgical treatment methods	+1
Participation of health ministry in granting of pharmaceutical patents	No	0
Opposition and pre-grant opposition to a patent	Observations during examination	+0.5
	Post granting in court only	-0.5
	Interdiction of pre-grant in FTA	-1
Extension of duration of the patent protection	In relation to patent granting	-1
	Mitigation – after a 4 years period	+0.5
	In relation to marketing authorization	-1
	Mitigation – no more than 2,5 years	+0.5
Compulsory licensing	Existence of an ex officio license, through administrative act with ground related to access to medicines	+2
	But no marketing of generic before the end of the patent	-1
	Very narrow provision on non voluntary license (limited grounds, no CL for public interest, procedure through court only)	-3
Parallel import	No	-1
Data exclusivity	5 years data exclusivity	-1
Linkage between patent and marketing authorization	Yes	-1
Experimental use - Bolar provision	Yes	+1
Other measures	Possibility to administration to take all possible measures to facilitate access to health over any type of protections	+1



TUNISIA



TUNISIA

In 2000, a new on patents was adopted in Tunisia to comply with the standards required by the World Trade Organization (WTO).

According to article 65.2 of the TRIPS agreement, Tunisia, like other “developing” countries, did not have to apply most of the provisions of the TRIPS Agreement until 1 January 2000. The new law 2000-84 entered into effect in August 2000.

Extension of patentability

The Tunisian law 2000-84 provides patent for products – which was one of the new requirement of the TRIPS agreement, in addition to requiring patent on production processes (art. 1). The law states that patents can be granted to “new invention”, that represent “an inventive step” and that can possible have an “industrial application”. These are basic principles set by the TRIPS agreement. Article 4 states that a new invention is not “included in the state of the technique” and defines what this means. The definition provided for “state of the technique” and “inventive step” (art. 5) would be useful in cases of patent opposition).

According to article 2, the law excludes the patentability of methods of surgical or therapeutic treatment, as well diagnostic methods as provided for by article 27.2 of the TRIPS Agreement, as well as formulations, products and compositions used to apply these methods. It also excludes from patentability of “living substances in nature”.

Contrary to Morocco, combinations or pharmaceutical compositions cannot be patented, neither can “new application” or “new use” of known patented products.

Existence of pre-grant opposition

Article 34 and following provide a procedure of opposition before the granting of a patent that can be launched within 2 months from the publication in the official bulletin of the filling of the patent. Such an action in court suspends the procedure of granting the patent.

A post grant opposition also exists and is stated by article 40. An action of post-grant opposition can be undertaken within one month from the date of the notification of the granting of the patent.

The delays to introduce an opposition, both pre-grant and post-grant, are very short which limits the use of these provisions. It gives a very limited time to prepare the action to court or implies that the person that undertakes it knew that the patent request was going to be introduced. The organization in charge of industrial property doing the examination and granting the patent has 18 months to publish the information in the official bulletin about the request filled.

Extension of the duration of the patent protection

There is no provision to extend the duration of the patent protection to compensate delays during the process of the grating of the patent or of granting of the marketing approval contrary to Morocco where such additional protections were introduced after the signing of an FTA with the US. The duration of the patent that was set to 20 years at the creation of the WTO (art. 36 of the Tunisian law), which already corresponded to an extension of the patent protection in most countries, was supposed to compensate for delays in the process of granting the patent or granting the marketing authorization.

However, a provision in the draft provided by the European union for the chapter on intellectual property of the free trade agreement (ALECA) currently under negotiation (art. 8.3) requires a complementary period of protection to compensate “the delay between the filing of the patent application and the first marketing authorization” that “may reduce the duration of the effective protection of the patent” (art. 8.3.1). In the draft,

the European Commission did not yet mention the number of years that they consider to a legitimate duration for the marketing approval process, beyond which an additional period of protection should be given (art. 8.3.2). The draft does not specify either a maximum of years of additional protection (art. 8.3.3) – in Morocco it cannot exceed two and a half years. An extra extension is also requested for medicines for which pediatric trials have been conducted – here also the exact duration of that extra extension in months is not specified yet in the draft (art. 8.3.4).

Limitation on compulsory licensing

Anybody can request a compulsory license but it can only be granted in three situations (art. 69):

- if the product has not been exploited industrially or if serious arrangements have not been taken to do so,
 - if the product has not been put on the market in enough quantity to satisfy domestic needs,
 - if industrial exploitation or commercialization of the product has been abandoned for more than 3 years in Tunisia.
- This is based on Art. 5.A(4) of the Paris convention that give conditions for compulsory licensing granted on the ground of “failure to work or insufficient working”. However, where the Paris convention states that the compulsory license may be requested 3 years after the granting of a patent or 4 years after filing of the application, article 51 of the Tunisian law (cited in article 69) add another 2 years for products that have to get a marketing approval before being put on the commercialized.

Furthermore, although the TRIPS agreement leaves states free to decide of the reasons why they want to use compulsory licensing, the Tunisian law does not include grounds for compulsory licensing based on the public interest or to counter anticompetitive behavior – which are two classic reasons often included in the law of WTO Member states.

The compulsory license can only be granted by a competent court, and before requesting a compulsory license an attempt to get a voluntary license from the patent holder must be undertaken (art. 70). The various aspects of the procedure for a compulsory license to be granted are states in articles 71, 72, 73, 74, 75, 76 and 77.

Article 78 introduces another form of compulsory licenses, ex officio licences, granted by an administrative decree: the minister of health can request from the minister of industry that patents covering medicines or processes to produce them be subjected to ex officio licenses when these medicines are not made available to the public in enough quantity or quality or are sold at “abnormally expensive prices”.

In article 49, a form of non government use is described: the minister of industry, at the request of the concerned authorities, can decide that despite the existence of a patent, equipment goods, accessories, spare parts can be imported to serve the public interest for non commercial use. However, the scope of this article does not seem to be able to include medicines, and does not mention local production.

Limitation of parallel import

The Tunisian law states (art. 47) that the rights granted by the patent do not cover the selling, the importation, the possession or the use of a patented product or a product obtain through a patented process, on the Tunisian territory once the product has been lawfully put on the market in a country by the patent owner or someone authorized by the patent owner. This describes a regime of international exhaustion of rights that allows parallel import from any country in the world.

However, the EU draft for the free trade agreement currently under negotiation states that parties have to apply either a national or regional regime of exhaustion of rights (the EU has a regional exhaustion regime and can do parallel import within the EU only). Accepting the EU draft would be a serious loss for Tunisia.



Data exclusivity

The decrees setting the conditions for the marketing of pharmaceutical products do not include data exclusivity provisions. However, the free trade agreement signed between Iceland, Liechtenstein, Norway, Switzerland and Tunisia in 2004 includes a provision requiring data exclusivity for at least 5 years. The agreement (Annex V, article 4) clearly states that parties shall prevent marketing approval of pharmaceutical products that are based, or referring to, non disclosed test data and other undisclosed data provided to the regulation authority in order to obtain marketing approval.

It is worth noting that the article 8.4 of the draft transmitted by the EU for the intellectual property chapter of the free trade under negotiation is introducing further constraints. The title of the article is “protection of the transmitted in order to gain marketing authorization for a medicine” but the content of the article is about data exclusivity (paragraph 2 and 3) and not just data protection (paragraph 1). Indeed, article 8.4 paragraphs 2 and 3 states that for a period of x years (number not specified yet) it will not be possible to refer to the pre-clinical and clinical data already submitted to the drug regulation authority in the process of requesting marketing authorization. This implies that even if a generic producers can prove that his/her product is bioequivalent to an original medicines the only possibility to get marketing authorization will be to re-do pre-clinical and clinical trials (which is not ethical): in other terms it will not be possible to register a generic. In case where the company that has marketed the first product get authorization for new indications for the same product within a certain period, article 8.4 paragraphs 4 states that the exclusivity of the data will be prolonged (the duration is not set yet in the draft). In Morocco the FTA with the US imposed a exclusive rights on the data required for the registration of a medicine for a minimum of 5 years, with an addition 3 years for new uses.

Linkage between patent and marketing authorization

There is currently no provision establishing a linkage between the patent status of a medicines and the marketing authorization.

Experimental use – Bolar provision

The “Bolar” provision, a provision that can be found in intellectual property laws, states that despite the existence of a patent covering an invention, third parties are allowed to work on it during the duration of the patent protection, without the agreement of the right owner. Among other things, it offers the possibility to generic manufacturers to prepare their product and conduct all the tests required by the regulatory authorities in order to obtain marketing authorization faster once the patent has expired.

Article 47 of the Tunisian patent law states that the rights conferred by the patent to not apply to “acts performed for experimental purposes” (47.b) or “acts necessary to the production of generic medicines” (47.e) – however, it clearly specifies that the commercial exploitation cannot take place before the end of the patent protection.

Scoring

Table 2: Scoring for Tunisia

Extension of patentability	No patentability of combinations	+1
	No patentability of methods of therapeutic or surgical treatment methods	+1
Participation of health ministry in granting of pharmaceutical patents	No	0
Opposition and pre-grant opposition to a patent	Pre-grant accessible to anybody but with court proceeding	+1
	Post-grant in court only	-0.5
Extension of duration of the patent protection	Nothing in the law the request from EU only a draft at the time of the study	0
Compulsory licensing	Narrow compulsory license (limited grounds, no CL for public interest, granted through court only)	-3
	Ex officio license (administrative act) and possibility to issue because of high price on medicines	+2
Parallel import	Yes	+1
Data exclusivity	No (except if EFTA provision implemented)	0
Linkage between patent and marketing authorization	No	0
Experimental use - Bolar provision	Yes	+1
Other measures	None	0





EGYPT



EGYPT

According to article 65.2 of the TRIPS agreement, Egypt, like other “developing” countries, did not have to apply most of the provisions of the TRIPS Agreement until 1 January 2000. A new law on the protection of intellectual property rights was passed in 2002 (Law n° 82) to update the law from 1949 and ensure that the Egyptian rules were compliant with the standards set by the World Trade Organization (WTO). It includes many of the flexibilities of the TRIPS agreement that can be applied in the field of public health.

Extension of patentability

The Egyptian law does not allow the patenting of diagnostic, therapeutic and surgical methods (art. 2(3)), nor the patenting of plants, animals, organs, tissues, live cells, natural substances, nuclear acid or genoma.

The patentability criteria are being “new”, involving an “inventive step” and being “industrially applicable” (art. 1). As there is no clear definition in the law of what is an “inventive step”, the interpretation of it is left to the examiner’s discretion. In the field of pharmaceuticals, examiners developed an internal policy.

According to the law a patent can be granted “for any modification, improvement or addition to a previously patented invention, which meets the criteria of being new, inventive and industrially applicable” (art. 1). In the case of pharmaceuticals, this can concern for instance a new and inventive process of production that improves a known product, or modifications of a chemical entity changing the action of the product. Since article 2(3) excludes therapeutic methods and article 2(2) excludes discoveries, patents on second uses of known products, on new posologies, or on combinations or pharmaceutical compositions cannot be granted in Egypt.

According to the internal policy of examiners, minor changes to known compounds or to chemical entities are not patentable, for lack of inventive step and/or because modifications are well known and expected by any person working in the field. This includes crystalline forms, salts, solvates, diastereomers, enantiomers, minor changes in the chemical structure that changes drug solubility and bio-availability, etc. New dosage forms of known products are also considered not patentable – unless the technique is new and the new form is an inventive way to solve a problem existing with the previous form.

Health ministry participation in analyzing pharmaceutical patents

The article 17 of Law 82 stipulates that the Patent Office “shall send to (...) the Ministry of Health, as required, copies of patent applications (...) that relate to (...) health significance, within 10 days from the examination of the application (...)”. The Minister of health has the possibility to oppose the acceptance of the application for the patent, or it may oppose the procedure to grant the patent when the acceptance of the application is made public. This will stop the procedure of granting the patent.

Existence of pre-grant opposition

A pre-grant opposition procedure is provided by article 16 to any party that can submit to the Patent Office a written notice opposing the grant of a patent within 60 days from the date of the publication of the application acceptance in the Patent Gazette. The opposition is subject to the payment of a fee – reimbursed if the opposition is accepted. It is worth noting that the period to submit the opposition is rather short.

Article 17 allows a pre-grant opposition from the part of the ministry of health (or the Ministries of Defence, Military production or Interior).



Extension of the duration of the patent protection

There does not seem to be any requirement to extend the duration of the patent protection over the 20 years of protection set by article 9 of Law n°82 in regulations concerning patents or marketing approval of pharmaceuticals. However, the European Free Trade Agreement (EFTA) signed between Iceland, Liechtenstein, Norway, Switzerland and Egypt in 2007 mentions that: “(...) the Parties shall ensure (...) that the procedures for grant or registration (...) permit the granting or registration of the right within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection.” (article 4).

Limitation on compulsory licensing

A compulsory license is granted by the Patent office, following approval from a Ministerial Committee established by the Prime Minister. The Committee sets the financial rights of the patent owner.

The grounds to grant compulsory licenses are (art. 23):

- For public non-commercial interest under the request of the competent Minister, including for the preservation of national security, health, environment and food safety.
- Cases of emergency or circumstances of extreme urgency.
- Support to national efforts in sectors of important for economic, social and technological development, without unreasonable prejudice to the patent owner’s rights and taking into account the legitimate interests of third parties.
- Upon the request of the Minister of health, if national needs for a patented medicine are not meet due to quantity or quality issues or because the price is “prohibitive”, or in cases of “critical cases, incurable or endemic diseases”.
- If the owner of the patent has failed to exploit the invention in Egypt, within 3 years from the granting of this patent or four years from the filling of the application (which correspond to Art. 5.A(4) of the Paris convention).
- If the owner of the patent has abused the rights derived from the patent or has exercised these rights in an anti-competitive manner: fixing exorbitant prices is one of the facts mentioned by the law.

Article 24 specifies various elements related to the issuing of compulsory licensing: each “non-voluntary license shall be considered on the merits of the case”, the patent owner has to be notified within a month of the grant of a license, etc.

When granted for public non-commercial interest or in cases of emergency or circumstances of extreme urgency no prior negotiations with the patent owner is required. However, that is not the case when compulsory licensing is used because of “prohibitive” prices on medicines.

Limitation of parallel import

The Egyptian law states in its article 10 paragraph 2 that “the right of a patent owner to prevent a third party from importing, using, selling or distributing a product” lapses when the patent owner “commercializes the product in any country”. Thus, Egypt adopted a regime of international exhaustion of right. As a consequence parallel imports are permitted from any countries in the world.

Data exclusivity

In 2000 a decree from the Prime Ministerial Decree No. 2211 established data protection, which means that according to article 39.3 of the WTO TRIPS agreement regulatory authorities have to protect the data they are receiving from companies from “disclosure” and from “unfair commercial use”. But the decree does not mention that a regulatory agency granting marketing approval cannot rely on data submitted regarding drug’s safety and effectiveness of a product to market a generic version of it.

In 2002, the company Pfizer tried to get Egyptian courts to establish data exclusivity. Pfizer had registered Lipitor® in Egypt and obtained market authorization in June 1998. No patent had requested yet and a patent application was submitted two months later and put in the “mail box”¹³. In December 2000, a generic version of the product was registered by the Egyptian International Pharmaceutical Industries Company (EIPICO). Pfizer filed a case in June 2002 arguing that the generic had been registered on the basis of clinical test data submitted by Pfizer and that this was contravening international rules on “undisclosed information”. After a long procedure, on 30 April 2005, the Zagazig Court found against Pfizer.¹⁴

In 2002, the law n°82 in its article 56 & 57 set data protection to be enforced by the competent authorities against disclosure and unfair commercial use “from the date of its submission to the competent authorities until it is no longer confidential, or for a period not exceeding five years”.

Contrary to free trade agreements that Iceland, Liechtenstein, Norway, Switzerland concluded with other countries (European Free Trade Agreement (EFTA)), the text they signed with Egypt does not require data exclusivity. It uses the same language as article 56 of law n°1982, calling for the protection against “disclosure and unfair commercial use”.

Linkage between patent and marketing authorization

There does not seem to be any provision establishing a linkage between the patent status of a medicines and the marketing authorization in the Egyptian law.

Experimental use – Bolar provision

The law n°82 in its Article 10 provides that for an exception for scientific research or experimental use from the right to prevent third parties from exploiting a patented invention. It does not specifically recognizes a Bolar-type provision allowing generic manufacturers to prepare their product and conduct all the tests required by the regulatory authorities in order to obtain marketing authorization faster once the patent has expired. However, the exemptions from patent exception listed in article 10 (in particular paragraphs 1, 5 and 6) should allow it. Of course, making it explicit in the law would be better.

Drug Stability Fund

Concerned by the impact of the new law on intellectual property n°82 on the price of pharmaceuticals, Egypt introduced in the law the creation of a “Drug Stability Fund” dedicated to “maintain stability in the prices of drugs” (article 18).

¹³- The TRIPS Agreement allowed for a 10-year transitional period in relation to pharmaceutical patents for countries that did not grant patent to products before TRIPS but only to processes. Such countries were required to establish a “mailbox” as soon as the agreement entered into force. Under this system patent owner could fill patent but those could only be granted from January 2005 on (Article 70(8)). The mailbox was established in Egypt in the year 2000, by virtue of Decree No. 547/2000 of the Prime Minister.

¹⁴- For more information see: Hossam Bahgat & Rebecca Wright (2010). Access to Medicines in Egypt: A Human Rights Approach to IP, Trade and Health in Access to Knowledge in Egypt: New Research on Intellectual Property, Innovation and Development, Edited by Nagla Rizk and Lea Shaver, Bloomsbury Academic, Bloomsbury Publishing.

Scoring

Table 3: Scoring for Egypt

Extension of patentability	No patentability of diagnostic, therapeutic and surgical methods	+1
Participation of health ministry in granting of pharmaceutical patents	Yes	+1
Opposition and pre-grant opposition to a patent	Post-grant opposition at patent office	+1
	Pre-grant for Minister of health	+0.5
Extension of duration of the patent protection	No extension in relation to patent granting	0
	No extension in relation to marketing authorization	0
Compulsory licensing	Non voluntary licenses with large grounds (public non-commercial interest, cases of emergency or circumstances of extreme urgency, request of health minister due to prohibitive price, abus of the rights or use in a manner contrary to fair competition, etc.)	+3
Parallel import	Yes	+1
Data exclusivity	No	0
Linkage between patent and marketing authorization	Non	0
Experimental use - Bolar provision	Yes, but not specific	+0,5
Other measures	Drug Price Stability Fund	+0,5

CONCLUSION: COMPARISON OF SCORES BETWEEN THE THREE COUNTRIES

This study provides a subjective assessment of provisions in different bodies of law and it not meant to provide a strict ranking for each country; however, they give a sense of the level of flexibilities within the intellectual property rules of the different countries in order to ensure access to medicines.

Under the current intellectual property landscape, the provisions in Egypt provide more flexibilities and do not contain intellectual property provisions imposing protections going beyond the level required by TRIPS. In Morocco, the conclusion of an FTA with the United States lead to the inclusion in the laws of additional constraints. Meanwhile, Tunisia contains some interesting provisions but could better make use of the TRIPS flexibilities (in particular on the grounds to issue compulsory licensing).

This methodology is meant to serve as a tool to assess the intellectual property landscape and its impact on access to medicines in any given country. It can be used to compare situations between countries and to identify different or new possibilities in other countries. It is meant for policy-makers, citizens and NGOs and was designed to be criticized, discussed, and improved upon.

	Morocco	Tunisia	Egypt
Extension of patentability	-1	+2	+1
Health ministry participation in analyzing pharmaceutical patents	0	0	+1
Health ministry participation in analyzing pharmaceutical patents	-1	+0,5	+1,5
Extension of duration of monopoly (Patent granting + Marketing authorization)	-1	0	0
Compulsory licensing	-2	-1	+3
Parallel import	-1	+1	+1
Data exclusivity	-1	0	0
Linkage between patent and marketing authorization	-1	0	0
Experimental use - Bolar provision	+1	+1	+0,5
Other	+1	0	+0,5
TOTAL	-6	+3,5	+8,5



Extension of patentability	Patentability of new uses	-1	No patentability of combinations	+1	No patentability of diagnostic, therapeutic and surgical methods	-1
	Patentability of combinations	-1				
	Not patentable methods of therapeutic or surgical treatment methods	+1	No patentability of methods of therapeutic or surgical treatment methods	+1		
Participation of health ministry in granting of pharmaceutical patents	No	0	No	0	Yes	+1
Opposition and pre-grant opposition to a patent	Observations during examination	+0,5	Pre-grant accessible to anybody but with court proceeding	+1	Post-grant opposition at patent office	+1
	Post granting in court only	-0,5	Post-grant in court only	-0,5	Pre-grant for Minister of health	+0,5
	Interdiction of pre-grant in FTA	-1				
Extension of duration of the patent protection	In relation to patent granting	-1	Nothing in the law the request from EU only a draft at the time of the study	0	No extension in relation to patent granting	0
	Mitigation – after a 4 years period	+0,5				
	In relation to marketing authorization	-1			No extension in relation to marketing authorization	0
	In relation to marketing authorization	+0,5				
Compulsory licensing	Existence of an ex officio license, through administrative act with ground related to access to medicines	+2	Narrow compulsory license (limited grounds, no CL for public interest, granted through court only)	-3	Non voluntary licenses with large grounds (public non-commercial interest, cases of emergency or circumstances of extreme urgency, request of health minister due to prohibitive price, abus of the rights or use in a manner contrary to fair competition, etc.)	+3
	Existence of an ex officio license, through administrative act with ground related to access to medicines	-1	Ex officio license (administrative act) and possibility to issue because of high price on medicines	+2		
	Existence of an ex officio license, through administrative act with ground related to access to medicines	-3				

Parallel import	No	-1	Yes	+1	Yes	+1
Data exclusivity	5 years data exclusivity	-1	No (except if EFTA provision implemented)	0	No	0
No (except if EFTA provision implemented)	Yes	+1	No	-1	No	-1
Experimental use - Bolar provision	Yes	+1	Yes	+1	Oui, mais pas spécifique	+0,5
Other measures	Possibility to administration to take all possible measures to facilitate access to health over any type of protections	+1	None	0	Drug Price Stability Fund	+0,5
TOTAL	MOROCCO	-6	TUNISIA	+3,5	EGYPT	+8,5



GLOSSARY

Compulsory license:

it is a legal provision according to which a government may allow a third party to use a patented product or process without the consent of the patent owner. It is one of the flexibilities on patent protection included in the WTO's agreement on intellectual property — the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement included to ensure a balance between private rights and public interest.

Data exclusivity:

Data exclusivity provides the originator with rights to preclude third parties from relying on the data submitted to the regulatory agency in order to obtain marketing approval for a pharmaceutical product for a specific period of time

Doha Declaration:

WTO Members adopted a special Ministerial Declaration at the WTO Ministerial Conference in Doha in 2001 to clarify ambiguities between the need for governments to apply the principles of public health and the terms of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In particular, the Doha Declaration stated that «Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted».

Intellectual property:

Intellectual property designates the various exclusive rights that cover creations of the intellect. The four main types of intellectual property rights are: patents, trademarks, design and copyrights.

Inventive step:

An invention is considered to include an inventive step if it is not obvious to a skilled person in the light of the state of the art. The inventive step is one of the most important criteria (along with novelty and industrial application) that need to be fulfilled in order to obtain a patent.

Marketing authorization:

An official document issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a pharmaceutical product after evaluation for safety, efficacy and quality.

Patent linkage:

Patent linkage involves linking generic drug marketing approval with the originator drug's patent status and refusing marketing approval until the relevant patent expires.

Patent opposition:

Opposition proceedings are designed to restrain the granting of illegitimate patents, for instance on frivolous or petty inventions. Depending of the law of the country, oppositions can take place pre-grant and post-grant. In some countries patent oppositions can be filed directly with the patent office, in others a more complicated process requires a court decision.

Parallel imports:

Parallel imports are the importation from another country of a patented product without the authorization of the patent owner. Parallel import is based on the legal notion of “exhaustion of rights” according to which a right owner is correctly and definitively remunerated once the product is put on a market. The regime of exhaustion of rights can be international, regional or national. The principle of national exhaustion of rights means that the right owner loses control on how it is resold on this market once the product is put on the national market, but can oppose importation of patented product from abroad. In case of international exhaustion of right, once the product is put on the market somewhere in world, the patent holder loses the authority to prevent parallel importation – that is importation from any place in the world.

Patent linkage:

Patent linkage involves linking generic drug marketing approval with the originator drug’s patent status and refusing marketing approval until the relevant patent expires.

Patentability:

Patentability is the ability of an invention to satisfy the legal requirements for obtaining a patent. The basic conditions of patentability, which an application must meet before a patent is granted, are that the invention must be novel, contain an inventive step (or be non-obvious) and be capable of industrial application. The invention also need to not be in certain fields that are excluded from patentability by the law.

Research/experimental use (Bolar provision):

Experimental use of a patented invention is allowed and does not constitute patent infringement as long as such use does not encroach upon the protected market. In some countries experimental use can permit clinical trials on a patented drug to ascertain the efficiency of a generic product so that it can be put on the market as soon as the patent expires.

Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement:

Agreement on trade-related aspects of intellectual property rights requires members to comply with certain minimum standards for the protection of intellectual property rights. But members may choose to implement laws that provide more extensive protection than is required in the agreement, so long as the additional protection does not contravene the provisions of the agreement. The WTO’s TRIPS agreement, negotiated in the 1986-94 Uruguay round, introduced intellectual property rules into the multilateral trading system for the first time.

TRIPS flexibilities:

These are provisions in the TRIPS agreement that provide countries with a degree of freedom in writing their regulations and national legislation to ensure a proper balance between the goal of protecting exclusive rights and the goal of protecting the general interest, in particular access to medicines.



ANNEX

LIST OF THE DOCUMENTS ANALYZED FOR THE STUDY

MOROCCO:

- *Law n°23-13 on industrial property*

<http://www.ompic.ma/sites/default/files/loi23-13FR.pdf>

- *Decree n°2-00-368 du 7 juin 2004 modified by the Decree n°2-05-1485 du 12 février 2006*

<http://www.wipo.int/edocs/lexdocs/laws/fr/ma/ma035fr.pdf>

<http://www.wipo.int/edocs/lexdocs/laws/en/ma/ma040en.pdf>

- *Law n°9-94 on the protection of plant varieties*

http://www.wipo.int/wipolex/en/text.jsp?file_id=128690

- *Law n° 17-04 on the code of medicine and of pharmacy*

<http://adala.justice.gov.ma/production/legislation/fr/civil/DahirMedicamentpharmacie.htm>

- *Circular on authorization for importation of medicines*

<http://www.sante.gov.ma/Reglementation/REGLEMENTATIONAPPLICABLEAUPRODUITSDESANTE/Circulaire%20relative%20%C3%A0%20proc%C3%A9dure%20d'authorisation%20d'importation%20de%20m%C3%A9dicaments%20et%20de%20dispositifs%20m%C3%A9dicaux%20%C3%A0%20titre%20de%20dons.pdf>

- *Decree n°2-12-198 on bioequivalence of generic medicines*

<http://www.sante.gov.ma/Reglementation/>

[REGLEMENTATIONAPPLICABLEAUPRODUITSDESANTE/2-12-198.pdf](http://www.sante.gov.ma/Reglementation/REGLEMENTATIONAPPLICABLEAUPRODUITSDESANTE/2-12-198.pdf)

- *Decree n°2-14-841 on marketing authorization of medicines*

<http://www.sante.gov.ma/Reglementation/>

[REGLEMENTATIONAPPLICABLEAUPRODUITSDESANTE/2-14-841.pdf](http://www.sante.gov.ma/Reglementation/REGLEMENTATIONAPPLICABLEAUPRODUITSDESANTE/2-14-841.pdf)

TUNISIA:

- *Law n°2000-84 of August 24, 2000 about patents for inventions*

<http://www.wipo.int/edocs/lexdocs/laws/fr/tn/tn001fr.pdf>

- *Decree n°2014-1039 of March 13, 2014 on regulation of public contracts*

http://www.legislation.tn/fr/detailtexte/D%C3%A9cret-num-2014-1039-du-13-03-2014-jort-2014-022__2014022010393?shorten=gyu0

- *Ministerial ruling on the creation of a technical committee on counterfeiting of medicines*

http://www.legislation.tn/fr/detailtexte/Arr%C3%AAt%C3%A9-num-2013-1923-du-28-11-2013-jort-2013-098__2013098019234?shorten=gyu0

• *Decree n°2010-1087 on the administrative and financial organization of the national insitut for the normalization and industrial property*

<http://www.legislation.tn/sites/default/files/fraction-journal-officiel/2010/2010F/041/TF201010873.pdf>

• *Decree n°67 of March 1, 1956 about patents for inventions*

<http://www.legislation.tn/sites/default/files/journal-officiel/1956/1956F/Jo01956.pdf>

• *Ministerial ruling of September 10, 1996 on marketing authorization for medicines*

<http://www.legislation.tn/sites/default/files/journal-officiel/1996/1996F/Jo07696.pdf>

• *Law n°85-91 of November 22, 1985 about the production and registration of medicines*

<http://www.legislation.tn/sites/default/files/journal-officiel/1985/1985F/Jo08485.pdf>

• *Free trade between EU and Tunisia (still under negotiation when the study was done)*

http://trade.ec.europa.eu/doclib/docs/2016/april/tradoc_154486.pdf

• *EFTA-Tunisia Free Trade Agreement*

<http://www.efta.int/media/documents/legal-texts/free-trade-relations/tunisia/annexes-protocols-rou-fr/CA94E7C874834CCDBEAA564D0FCDF0B6.pdf>

EGYPT:

• *Law n°82 of 2002 pertaining to the protection of intellectual property rights*

<http://www.wipo.int/edocs/lexdocs/laws/en/eg/eg001en.pdf>

• *Prime Ministerial Decree 2211/2000 regarding the Confidentiality of Information Related to Africultural and Pharmaceutical Chemical Products*

<https://www.google.be/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwj2rY6Un5DRAhWXO1AKHUr1DIEQFggcMAA&url=http%3A%2F%2Fwww.who.int%2Fintellectualproperty%2Ftopics%2Fip%2Fen%2FData.exclusivity.review.doc&usg=AFQjCNHA9gFafPdZuKA9-LhWWdep4UnKgAurl?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwj2rY6Un5DRAhWXO1AKHUr1DIEQFggcMAA&url=http%3A%2F%2Fwww.who.int%2Fintellectualproperty%2Ftopics%2Fip%2Fen%2FData.exclusivity.review.doc&usg=AFQjCNHA9gFafPdZuKA9-LhWWdep4UnKgA>

<https://www.google.be/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwj2rY6Un5DRAhWXO1AKHUr1DIEQFggcMAA&url=http%3A%2F%2Fwww.who.int%2Fintellectualproperty%2Ftopics%2Fip%2Fen%2FData.exclusivity.review.doc&usg=AFQjCNHA9gFafPdZuKA9-LhWWdep4UnKgA>

<http://www.who.int%2Fintellectualproperty%2Ftopics%2Fip%2Fen%2FData.exclusivity.review.doc&usg=AFQjCNHA9gFafPdZuKA9-LhWWdep4UnKgA>

<http://www.who.int%2Fintellectualproperty%2Ftopics%2Fip%2Fen%2FData.exclusivity.review.doc&usg=AFQjCNHA9gFafPdZuKA9-LhWWdep4UnKgA>

<http://www.who.int%2Fintellectualproperty%2Ftopics%2Fip%2Fen%2FData.exclusivity.review.doc&usg=AFQjCNHA9gFafPdZuKA9-LhWWdep4UnKgA>

<http://www.who.int%2Fintellectualproperty%2Ftopics%2Fip%2Fen%2FData.exclusivity.review.doc&usg=AFQjCNHA9gFafPdZuKA9-LhWWdep4UnKgA>

<http://www.who.int%2Fintellectualproperty%2Ftopics%2Fip%2Fen%2FData.exclusivity.review.doc&usg=AFQjCNHA9gFafPdZuKA9-LhWWdep4UnKgA>

<http://www.who.int%2Fintellectualproperty%2Ftopics%2Fip%2Fen%2FData.exclusivity.review.doc&usg=AFQjCNHA9gFafPdZuKA9-LhWWdep4UnKgA>

• *Minister Decree n°370/2006*

<http://www.eda.mohealth.gov.eg/Articles.aspx?id=26>

• *Minister Decree n°296/2009: Registration of Human Drug*

http://www.eda.mohealth.gov.eg/Files/661_MinisterDec296.pdf

• *Presidential Decree n°113/1962*

http://www.eda.mohealth.gov.eg/Files/111_Presidential_Decree_113-1963.pdf

• *Pricing Ministerial Decree n°499/2012*

http://www.eda.mohealth.gov.eg/Files/112_499.pdf



• *Ministerial Decree n°575/2012*

http://www.eda.mohealth.gov.eg/Files/113_575.pdf

• *Ministerial Decree n°622/2012*

http://www.eda.mohealth.gov.eg/Files/650_622-2012.pdf

• *Ministerial Decree 425/2015 Registration of Human Pharmaceuticals*

http://www.eda.mohealth.gov.eg/Files/766_425_2015.pdf

• *Euro-Mediterranean Agreement between EC and Egypt (2004)*

http://trade.ec.europa.eu/doclib/docs/2004/june/tradoc_117680.pdf

• *EFTA States Free Trade Agreement with Egypt (2007)*

<http://www.efta.int/media/documents/legal-texts/free-trade-relations/egypt/Annexes%20and%20Protocols/EG-FTA-Annex-V-IPR.pdf>



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