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# Intellectual Property Rights: Potential Implications of the DCFTA for Access to Medicine

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## I. Introduction

As part of its policy of increasing exports and its objective of greater integration into the global economy, Tunisia has signed on to several agreements in recent years. By joining the World Trade Organization (WTO) in 1995, Tunisia signed the General Agreement on Tariffs and Trade (GATT), making a large number of commitments related to dismantling the limitations on market access to its network industries. These commitments include the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS), which is an international legal agreement between the members of the WTO, setting the standards for Intellectual Property (IP) rights. In the same year, Tunisia joined the Maghreb Union (MU) and signed the Association Agreement (AA) with the European Union (EU), to liberalize trade between them in the industrial sector.

Meanwhile, the EU's strategies have shifted from a regional approach, with the cooperation agreements<sup>1</sup> and AAs<sup>2</sup>, to a country-specific approach, in the form of Neighbourhood Action Plans<sup>3</sup> and Free Trade Agreements (FTAs). Hence, since October 2015, Tunisia has been involved in negotiations for the Deep and Comprehensive Free Trade Agreement (DCFTA) with the EU. In line with the AAs, the DCFTA will go further with the "Comprehensive" and "Deep" dimensions of this agreement and, once signed, will require Tunisia to undertake profound and irreversible changes in its national public policies. The texts of the DCFTA as proposed by the EU were presented in the first preliminary discussions and have since been updated in subsequent rounds of negotiations. The texts are subdivided in 14 domains, with a specific one related to the IP.

This paper draws attention to the IP rights in Tunisia as a TRIPS signatory. It will discuss the provisions included in the proposed DCFTA's IP chapter and their potential impact on access to medicine in Tunisia.

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<sup>1</sup> Cooperation Agreement with Tunisia entered into force between 1978 and 1979

<sup>2</sup> Association Agreement in 1995 with Tunisia ratified in 1995 and entered into force 1998

<sup>3</sup> Tunisia adopts EU - Tunisia Neighborhood Action Plan in 2006



## II. Intellectual Property laws

### 1. Intellectual Property rights

The term Intellectual Property (IP) refers to intangible property, specifically related to information, which can be incorporated into tangible objects and may be claimed by individuals, enterprises or other entities<sup>4</sup>. Intellectual Property Rights (IPRs) are the exclusive rights to use the protected information carried by these objects. It can deal with a product or process that provides a new way of doing something, or that offers a new technical solution to a problem. IPRs include mainly patents, copyrights, trademarks, industrial designs, trade secrets and geographical indications. Hence, IPRs exclude the use of a creation without the creator's consent for a limited time period in the countries where the patent has been registered<sup>5</sup>.

### 2. Trade-related aspects of intellectual property rights (TRIPS)

Historically, intellectual property laws first emerged with the establishment of the patent system in 1400 in Venice. However, it was only in the late 1800s that IP laws started to develop as an independent normative field. Over time, IP laws were developed and different international bodies established to govern the international IP regime (see Box 1). The stated aim of these organizations is to develop a balanced and effective international IP system that enables innovation and creativity for the benefit of all

#### Box 1 :

##### Organization involved in IP

**World Intellectual Property Organization (WIPO)** was established in 1893 and formerly called the United International Bureau for the protection of the intellectual property. The first convention regarding the protection of industrial property rights i.e. Paris Convention, was held in Paris in 1883. This international agreement covers inventions (patents), trademarks as well as industrial designs and was the first major step taken to help creators to ensure that their work is protected in other countries. Where after, in 1886, the second convention covered the literary and artistic work and established the copyright system.

**World Trade Organization (WTO)** also adopted different IP regulations within the international trade system framework. The linkage between the WTO and the WIPO was the result of an initiative of an US-bases industries group, to establish a framework for IP protection and its enforcement and to bring IP as a "trade-related" issue into the GATT (Correa, 2010). Thus, according to the WIPO and the WTO, IP laws strive to establish a balance between a social long-term objective, to provide incentives for inventions and creative activities, and a short-term objective that enables the public to use these inventions and the existing creative activities.

**World Health Organization (WHO)** as a specialized agency of the UN system is operating under the international human rights law. It is directing and coordination authority for health within the UN system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends.

<sup>4</sup> Training tools on the TRIPS agreement: The developing countries' perspective (2002) UNCTAD, Commercial Diplomacy Program.

<sup>5</sup> World Trade Organization - [Overview: the TRIPS Agreement](#)

Nowadays, the most comprehensive international agreement on IP is the TRIPS Agreement. The negotiation of the TRIPS Agreement took into consideration and supplemented, with additional obligations, some of the past international agreements, namely the Paris Convention for the Protection of Industrial Property (1967), the Berne Convention for the Protection of Literary and Artistic Works (1971), the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations (the Rome Convention) (1961) and the Washington Treaty on Intellectual Property in respect of Integrated Circuits (1989).

The TRIPS Agreement of the WTO is the first and remains the most comprehensive international agreement on IP until today. Coinciding with the end of the Uruguay Round and the creation of the WTO, the TRIPS is a multilateral trade agreement which forms minimum standards for the regulation of IP, including copyright and related rights, as well as industrial property rights. It was later introduced into the international trading system with the claimed aim of facilitating the emergence of the global economy through the creation of a safe environment for investment and trade.

In respect of each of the intellectual property areas covered, the TRIPS Agreement sets out the protection standards to be provided by each signatory party. The Agreement delineates guidelines for the following areas: the subject-matter to be protected, the rights to be conferred as well as permissible exceptions to those rights, and the minimum duration of protection. The Agreement lays down provisions for internal procedures and corrective measures to enforce intellectual property rights, i.e. comprehensive civil and administrative remedies, special requirements for border measures and criminal procedures to ensure effective enforcement of the Agreement<sup>6</sup>.

However, a number of countries opposed TRIPS when it was first introduced<sup>7</sup>. The controversy caused by TRIPS, along with the intense pressure made by the civil society and the international community, initiated a round of talks and resulted in the Doha declaration in November, 2001<sup>8</sup>. The declaration clarified the scope of the TRIPS and promoted access to medicine for all, where it was stated that “it is important to implement and interpret the TRIPS Agreement in a way that supports public health — by promoting both access to existing medicines and the creation of new medicines.”<sup>9</sup> The declaration recognized both the importance of enabling equitable access to new drugs and regulating the effect of IP on medicine pricing<sup>10</sup>. Two main provisions were subsequently accorded to developing countries and least developed countries under the TRIPS. These provisions included a set of “direct flexibilities” (see Box 2), as well as a transitional period of 10 years, the main purpose of which was to promote public health and access to medicine.

The TRIPS agreement also contains “indirect flexibilities” (see Box 2), offering a space for countries to adjust their patent laws according to policies and needs<sup>11</sup>. For instance, the two main standards on which a patent should be granted, namely “novelty” and the “inventive-step”<sup>12</sup> (see Box 3), were either left undefined or defined while giving enough freedom for interpretation. Also, the WTO has barely defined the terms in its patentability standards. Thus, these ambiguous definitions give the space to countries to adjust the definition and restrict it based on its own needs and policies. This is an important example where developing countries were able to turn TRIPS to their advantage mainly due to the support of civil society actors, who helped with technical expertise and through global campaigning<sup>13</sup>.

<sup>6</sup> *ibid.*

<sup>7</sup> During the Uruguay round in 1994

<sup>8</sup> [Declaration on the TRIPS agreement and public health. Adopted on 14 November 2001. DOHA WTO Ministerial 2001: TRIPS WT/MIN \(01\)/DEC/2. Geneva: World Trade Organization; 2001..](#)

<sup>9</sup> *ibid.*

<sup>10</sup> Correa C.M. (2002) *Implications de la déclaration sur l'accord sur les ADPIC et la santé publique adoptée à DOHA. Geneva: World Health Organization.*

<sup>11</sup> Correa C.M. (2013). *Intellectual Property Rights and Public Health: The General Context and Main TRIPS-Compliant Flexibilities. Intellectual Property and Access to Medicines. South Center, WHO. pp 13-28.*

<sup>12</sup> *In order to be patentable, an invention usually needs to meet the requirements of novelty, inventive step (or non-obviousness) and industrial applicability (or usefulness).*

<sup>13</sup> Drahos P. (2003). *Expanding Intellectual Property's Empire: The Role of FTAs. International Centre for Trade and Sustainable Development.*

## Box 2 :

### Direct Flexibilities in TRIPS

**Compulsory license** allows the exploitation of a patent during the patent term without the consent of the patent holder, but with the authorization of competent national authorities. This authorization may be given to a third party, or, in the case of government use (a **Public non-commercial use licence**) to a government agency or to a third party authorized to act on the government's behalf. The term «compulsory licensing» is often used to refer to both forms of authorization, although they can have important operational distinctions. WTO members have the freedom to determine the grounds upon which compulsory licences are granted. They are thus not limited to emergencies or other urgent situations.

**Parallel import** can be a significant way of increasing access to medications, where the prices charged by patent holders for their products are unaffordable. Moreover, in situations where the local manufacture of the product is not feasible, and therefore compulsory licenses may be ineffective, parallel importation may be a relevant tool to ensure access to drugs.

**Bolar exception** or **Regulatory review exception** under which generic companies can use patented inventions for the purposes of obtaining regulatory authorization for the prompt marketing of their generic versions after the expiry of the patent. Under this framework, the Bolar exception is of particular importance and provides a valuable tool for stimulating competition in the market and ensuring the protection of public health.

### Indirect Flexibilities or Non-patent-related measure in TRIPS

**Adoption of the transition period** granted by Article 66.1 of TRIPS to the least-developed country, during which they are not obligated to enforce certain provisions of the TRIPS agreement.

**Patentability criteria** relative freedom in determining their patentability criteria spelled out in Article 27.1, read together with article 1.1, Article 7 and Article 8.

**Declaration of no patent in territory** under which generic medicines are allowed to be produced after a declaration that there was no relevant patent in the territory. Strictly, this is not a TRIPS flexibility. However, generic medicines can be procured despite patents actually being registered in other territory.

**Import authorization without reference** to patent status allowing the import of a patented product into a country without the authorization of the title holder, to the extent that the product has been put on the market elsewhere in a legitimate manner.

**For more information, see: [www.wto.org](http://www.wto.org)**

As a developing country, Tunisia was granted a 10-year transitional period to prepare for national implementation of the WTO Agreement provisions on Intellectual Property. Within the period of 5 years, the first patent law was issued on 24 August 2000. However, this law was only brought into force by the end of the transition period in 2005. The current Tunisian patent law<sup>14</sup> contains 14 chapters, including the patentability standards, the different licensing procedures and conditions, the rights and obligations of each patent holder as well as the different measures in case of patent infringement.

<sup>14</sup> Law no. 2000-84 of August 24, 2000, on Patents

<sup>15</sup> Gaëlle Krikorian, Head of Policy, MSF. During the national seminar “intellectual property from a development perspective”, 21-23 February, Tunis.

<sup>16</sup> Official declaration of the National Institute of Standardization and Industrial Property, during the national

<sup>17</sup> Gurgula O. (2019) The ‘obvious to try’ method of addressing strategic patenting: How developing countries can utilize patent law to facilitate access to medicines. Policy Brief n° 59. South Center.

The IP law in Tunisia is identical to the minimum covered by the TRIPS agreement and the French patent law. It is perfectly reliable and in compliance with international standards<sup>15</sup>. Plus, Tunisia has successfully adopted direct TRIPS flexibilities into its patent law. For instance, article 69 - 77 deals with “compulsory licensing” and “ex officio licensing” while article 47, covers as the “Bolar exception” (see definitions in Box 2). The “parallel import flexibility” was the only flexibility that was not included since the imports of medicine are centralized by Tunisia’s state-run Central Pharmacy (Pharmacie Centrale de Tunisie).

However, indirect TRIPS flexibilities are less exploited in the Tunisian IP law<sup>16</sup>. When reviewing the patentability criteria in the Tunisian law (articles 4, 5 and 6), which includes “novelty”, “inventive-step” (see Box 3 for definition), and manufacturing applicability, we notice that these steps were briefly defined in the Tunisian IP law with no further indications nor restrictions. This barely defined criteria can have a major impact on the Tunisian pharmaceutical sector through the proliferation of patents or the “evergreening process”. Due to its inherent nature, an active ingredient of a pharmaceutical product may exist in different physical forms and formulations and can be used in different administering forms, different release methods and can have different therapeutic effects and even treat different diseases. Once the new forms, formulations, uses or processes of a known active ingredient are discovered, a pharmaceutical company can ask for a patent protection on these modifications<sup>17</sup>. This patent expansion, called the “evergreening process”, aims to block or delay competition through the patenting of derivatives or variants of an existing product as well as their method of use like formulations, dosages, etc. It has the capacity to significantly extend the market exclusivity of a pharmaceutical product beyond the term of protection provided by the active product patent. The evergreening is especially problematic for access to medicine, because they keep competing, possibly less expensive generic products off the market.

### Box 3

#### Patentability requirement

**Novelty** is a requirement to patentability. An invention can be patented only if it is new. An invention is considered to be new if it does not form part of the state of the art i.e. unknown to the public before the patent application date.

An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. Hence, an invention should be sufficiently inventive i.e. non-obvious, in order to be patented.

<sup>18</sup> Correa, C.M. (2013). *Intellectual Property Rights and Public Health: The General Context and Main TRIPS-Compliant Flexibilities*. in *Intellectual Property and Access to Medicines*. South Center, WHO, pp. 13-28.

In fact, there are several countries that already protect themselves against this process, in order to prevent the proliferation of patents. For example, the Indian law, states that: “From a public health perspective, it has been suggested that patents should not be granted where the claimed subject matter consists of polymorphs, isomers, active metabolites, dosages or new indications of known medicines, and that patent applications should normally be rejected (due to lack of inventive step) where salts, esters or formulations are claimed”<sup>18</sup>. Thus, the India’s Supreme Court had the ability to refuse to grant Swiss pharmaceutical company Novartis a patent for a new version of its cancer drug Gleevec (Imatinib), used to fight leukemia. Novartis claims the drug is more easily absorbed into the blood and that is enough of an improvement to warrant patent protection. But India has been able to protect itself against the abuses associated to patent applications, thanks to its patent law. The best way to avoid evergreening is to incorporate detailed criteria in the Tunisian law as allowed by the indirect TRIPS flexibilities.

The Tunisian IP law can likewise be amended to better integrate the TRIPS indirect flexibilities, to limit risky processes such as evergreening so as to not obstruct public health policies. However, with the entering into force of the EU’s AA in 1995, it appears Tunisia’s ability to ameliorate its IP law has been hindered.

### III. Free Trade agreements and TRIPS+

Tunisia’s joining the WTO and reforming its IP law coincided with the entering into force of the AA between Tunisia and the EU in 1995, enabling the potential influence of the AA on IP legal reforms<sup>19</sup>.

The AA was concerned with ensuring Tunisia adopt the required “reforms” to facilitate the free movement of capital and goods, with provisions on payments, capital, competition and other economic provisions<sup>20</sup>. However, the 39th article of this agreement<sup>21</sup> includes a provision requiring the two parties to ensure an effective and adequate protection of commercial and industrial property rights in compliance with the “highest international standards”. Yet, the “highest international standard” is an ambiguous term since no specific treaty, whether multilateral or bilateral, is mentioned as being the standard. In general, when an agreement refers to the highest international standards of protection, it is presumed that this concept may include any standards adopted under an international instrument which is recognized and accepted by all parties<sup>22</sup>. In other words, adding vagueness and inconsistency in the interpretation of these provisions paves the way for standards that are “higher” than those included TRIPS agreement<sup>23</sup>.

It is now widely accepted that the inclusion of IP protections in trade negotiations driven by developed countries is motivated by going beyond the TRIPS provisions, in order to shore up the interests of innovators in the developed world. Indeed, developed countries consider that the TRIPS Agreement is not being enforced adequately by many developing countries and is insufficient to protect their interests at the global scale<sup>24</sup>. As Tunisia is currently in negotiations with the EU on a new FTA with a specific chapter related to the IP<sup>25</sup>, Tunisia is contributing to the establishment of a new “highest international standard” to which it must abide.

Known as part of the new wave agreements negotiated outside of the WTO<sup>26</sup>, the DCFTA proposed by the EU to Tunisia derogates from existing standards and very often sets new ones. These kinds of free trade agreements require even higher levels of intellectual property protection than those provided by TRIPS<sup>27</sup>. Called TRIPS+ standards, these provisions require extending the patent term, introducing provisions that limit the use of TRIPS flexibilities or restricting generic competition<sup>28</sup>. There is no obligation in international law to apply TRIPS+ provisions, since the TRIPS

<sup>19</sup> El Euch M. (2008) *Fondements juridiques des dispositions relatives à la propriété industrielle dans l'accord d'association entre la Tunisie et la Communauté Européenne* - Université El Manar de Tunis – Mémoire de master professionnel en droit de la propriété intellectuelle.

<sup>20</sup> Chandoul J. (2017) *DCFTA: a key instrument of EU policy*. Briefing paper n°2. Tunisian Observatory of Economy.

<sup>21</sup> [Accord euro-méditerranéen établissant une association entre la Communauté européenne et ses états membres d'une part et d'autre part la république tunisienne](http://www.oleca.tn/). *Journal officiel des Communautés européennes* L 97/2 30.3.98

<sup>22</sup> See EU-Tunisia AA 1998, Annex 7

<sup>23</sup> World Health Organization, *Regional Office for the Eastern Mediterranean* (2010) *Public health related TRIPS-plus provisions in bilateral trade agreements: a policy guide for negotiators and implementers in the WHO Eastern Mediterranean Region*.

<sup>24</sup> Vawda Y.A., Shonzi B. (2020) *Eighteen Years After Doha: An Analysis of the Use of Public Health TRIPS Flexibilities in Africa*. South Center Research Paper No.103. South Center. <http://www.oleca.tn/>

<sup>25</sup> Chandoul J. (2017) *DCFTA: a key instrument of EU policy*. Briefing paper n°2. Tunisian Observatory of Economy.

<sup>27</sup> Drahas, Peter. (2003). *Expanding Intellectual Property's Empire: The Role of FTAs*.

<sup>28</sup> Correa C.M. (2006) *Implications of bilateral free trade agreements on access to medicines*. *Bulletin of the World Health Organization*. 84 (5), pp. 399-404.

Agreement establishes minimum standards of protection for IPRs. WTO Members cannot confer a lower protection level that established in the TRIPS agreement. On the other hand, those Members are protected against demands by other Members to confer a higher level of protection. Unless they are part of FTAs with TRIPS+ provisions outside of the WTO system, in which case those Members have no choice but to adopt TRIPS+<sup>29</sup>.

Found in FTAs between the US or the EU and Oman, Peru, Australia and Morocco, TRIPS+ are described as a drastic obstacle for public health issues, since they not only limit the TRIPS flexibilities but also impose additional obligations on states.<sup>30,31</sup>

There has been a growing literature alerting to the negative effects and implications of TRIPS+ on limiting the freedom of developing and least developed countries to devise policies compatible with their level of progress and development on public health<sup>32</sup>. The WHO, for example, “recommends that developing countries be cautious about enacting legislation that is more stringent than the TRIPS requirements”<sup>33</sup>.

In the Tunisian context, a treaty was already signed in 2017 by the European Patent Office and its Tunisian equivalent. This treaty represents a new restriction on access to medicines outside the TRIPS agreement. This treaty stipulates that patents for new medicines declared in the EU will also enter into force in the Tunisian territory, which goes beyond the TRIPS provision, preventing Tunisia from producing a large proportion of the newest generation medicines in generic form<sup>34</sup>. In addition, this treaty limits a number of TRIPS flexibilities such as “Declaration of no patent in territory” or the “Import authorization without reference to patent status”, which are allowed under the TRIPS Agreement, but blocked by this treaty.

As with the DCFTA TRIPS+ provisions, and similar to other FTAs signed between developing countries and the EU, once signed Tunisia will have no choice but to adopt TRIPS+. In the event that the DCFTA is actually signed, the TRIPS+ provisions in this bilateral trade agreement will commit Tunisia to major legislative and legal changes that contain a number of threats and raise concerns among health and drug professionals.<sup>35,36,37</sup>

## VI. Impact of the DCFTA on access to medicine

The IPR provisions for Tunisia proposed by the EU in the DCFTA, go beyond what the Tunisian IP law covers already, and thus will have an impact on the local production of generics, the accessibility and affordability of drugs as well as the role and prerogatives of the different intervening national structures in charge.

### 1. IP rights: Expanding the protection period

To protect public health and ensure the availability of high quality, safe and effective medicines for citizens, all medicines must be authorized before being on market. This marketing authorization is granted after running lab and clinical tests that confirms the safety and efficiency of the drug. This protection can transform into a market monopoly only in cases where the medicine is authorized for sale by national authorities via the marketing authorisation.

It is important to note that there are instances where a patented medicine does not receive marketing authorization. In fact, having a patent on a new substance/drug does not guarantee its marketing. For example, a pharmaceutical company can have a patent on an invention (e.g. new medicine) but find itself unable to put this invention on the market if they are unable to prove its safety and efficiency.

However, a medicine can be granted a marketing authorization without being patented. This is the case of generic medicines, which are medicinal products having the same qualitative and quantitative composition as the original products and whose bioequivalence has been demonstrated by appropriate studies. Generic

<sup>29</sup> Article 1.1. [Trade-Related Aspects of Intellectual Property Rights. Part I – General Provisions and Basic Principles.](#)

<sup>30</sup> Correa C.M. (2006) Implications of bilateral free trade agreements on access to medicines. *Bulletin of the World Health Organization*. 84 (5), pp. 399-404.

<sup>31</sup> Halbert D.J. (2017) *The Curious Case of Monopoly Rights as Free Trade: The TPP and Intellectual Property and Why It Still Matters.* *Journal of Information Policy*, Vol. 7, pp. 204-227.

<sup>32</sup> World Health Organization, *Regional Office for the Eastern Mediterranean (2010) Public health related TRIPS-plus provisions in bilateral trade agreements: a policy guide for negotiators and implementers in the WHO Eastern Mediterranean Region*

<sup>33</sup> [World Health Organization \(2001\) Globalization, TRIPS and access to pharmaceuticals. World Health Organization.](#)

<sup>34</sup> [En Tunisie, un accord avec l'UE menace de faire flamber le prix des médicaments](#)

<sup>35</sup> [Conseil national de l'Ordre des pharmaciens : « L'Aleca risque de pénaliser le marché des médicaments en Tunisie »](#)

<sup>36</sup> [En Tunisie, un accord avec l'UE menace de faire flamber le prix des médicaments](#)

<sup>37</sup> [ALECA / Tunisie : « lire attentivement la notice »](#)



medicines are pharmaceutical products with proven efficacy and which are no longer protected by patents. The emergence of generic drugs allows for a reduction in the price of drugs through competition. On the contrary, a longer patent protection means longer market monopoly standing and hence less competition from other producers<sup>38</sup>.

In practice the patent protection period of any drug is set to 20 years. Usually it takes up to 12 years to get a patent and the first marketing authorization<sup>39</sup> gives the producer only 8 years of market monopoly. The extension of the patent term is presented in the DCFTA as a compensation for the reduced period: indeed, since the patent protection starts from the day the inventor files for a patent, and not from the date he/she gets his marketing authorization, the effective term of patent protection is reduced. The new protection period is supposed to equal to the time lost waiting for the marketing authorization purchase<sup>40</sup>. In addition, all medicine that underwent paediatric studies of which the results appear on the product information will be granted an additional protection period of [X] months<sup>41</sup>.

Knowing that developing countries rejected this particular European and United States demand during the Uruguay Round, it appears that the EU is reopening this issue under bilateral trade agreements with developing countries and for Tunisia under the DCFTA proposal<sup>42</sup>.

However, in the specific case of Tunisia, the time required to examine a marketing authorization application submitted under the national procedure has already been shortened<sup>43</sup>. The national agency for the drugs and health products safety has recently shortened the required time to examine an application for a requested marketing authorization<sup>44</sup>, and is therefore already in compliance with the European directive<sup>45</sup>.

On the other hand, some are questioning the real interest behind the inclusion of this compensation in the FTA. As this time compensation is mainly related to the R&D costs in the case of commercially successful medicines, these costs are likely to be already recovered by several months of sales at the prices that can be charged in isolation from competition, under the exclusive rights enjoyed by the patent owner<sup>46</sup>. As the drug industry is heavily reliant on patents the real reason for the time extension is to restrain competition and delay the entry of generic competition. As discussed above, the patent protection leads to higher drug prices than those of their generic counterparts. Hence, the longer the term of the patent, the longer it takes to reduce drug prices and the longer the drug industry can benefit from it<sup>47</sup>. Hence, this extension of the patent term would mean that many people would not be able to afford treatment for many more years.

Nevertheless, developing countries are urged to improve their patent laws to prevent strategic patenting and promote competition and access to medicines<sup>48</sup> rather than allowing patent term extension. In fact, only a few patents actually protect new active ingredients; the majority of existing patents cover logical extensions of existing knowledge or developments that are patented with the deliberate aim of delaying competition<sup>49</sup>. As mentioned above, since Tunisia is not protected against this “evergreening process”, the entry into force of DCFTA will make the country even more vulnerable to the proliferation of patents.

In addition, it is unclear if this provision includes extensions only to marketing authorization delays in the country where it is sought or whether the delays will also apply to the countries where the first approval was obtained. This clarification is important since in the case of the FTA between USA and Bahrain, the latter has been obligated to also take into account the delays in a foreign country, which leads to further extension on the patent's term<sup>50</sup>. In the case of the EU's proposed DCFTA, the number of years will be set at a later date during the negotiations with a maximum number of years not to be exceeded<sup>51</sup>. Yet, when we take into consideration the years

<sup>38</sup> World Health Organization, Regional Office for the Eastern Mediterranean (2010) *Public health related TRIPS-plus provisions in bilateral trade agreements: a policy guide for negotiators and implementers in the WHO Eastern Mediterranean Region*

<sup>39</sup> Van Norman, Gail A. (2016). *Drugs, Devices and the FDA: Part 1: An Overview for Approval Processes for Drugs*. JACC: *Translational to Science*, 1(3), pp. 170-9

<sup>40</sup> [X years]: the number of years will be set later during the negotiations

<sup>41</sup> Article 44, [Protection of intellectual property](#). The texts proposed by the EU for a Deep and Comprehensive Free Trade Area (DCFTA) with Tunisia, Updated on 31 July 2018

<sup>42</sup> World Health Organization, Regional Office for the Eastern Mediterranean (2010) *Public health related TRIPS-plus provisions in bilateral trade agreements: a policy guide for negotiators and implementers in the WHO Eastern Mediterranean Region*

<sup>43</sup> [Optimisation des délais d'instruction d'une demande d'AMM soumise en procédure nationale](#)

<sup>44</sup> For applications submitted after October 1, 2019

<sup>45</sup> Application of Article 17(1) of the amended directive 2001/83/EC.

<sup>46</sup> Correa C.M. (2006) *Implications of bilateral free trade agreements on access to medicines*. *Bulletin of the World Health Organization*. 84 (5), pp. 399-404.

<sup>47</sup> Correa C. M. (2004). *Ownership of knowledge—the role of patents in pharmaceutical R&D*. *Bulletin of the World Health Organization*, 82(10), 784–790.

<sup>48</sup> *ibid.*

<sup>49</sup> *ibid.*

<sup>50</sup> FTA Article 15.6. (b) (ii) in Correa C.M. (2006) *Implications of bilateral free trade agreements on access to medicines*. *Bulletin of the World Health Organization*. 84 (5), pp. 399-404.

<sup>51</sup> Article 44, [Protection of intellectual property](#). The texts proposed by the EU for a Deep and Comprehensive Free Trade Area (DCFTA) with Tunisia, Updated on 31 July 2018.

that will be added for the delays in obtaining authorization both at the national level and foreign levels, in addition to the months added in the case of medicinal products that have been the subject of paediatric studies and the evergreening process, it seems Tunisia will find itself locked into endless patents.

The above analysis would explain the current Tunisian orientation during the DCFTA negotiations rounds. From the Tunisian side, it has been argued that the strengthening of IPR may restrict access to medicines with negotiators calling for a restriction of IPR to TRIPS requirements since the first rounds of discussions<sup>52</sup>, and rejecting the extension of patent term for drugs in subsequent rounds<sup>53</sup>.

## 2. Data exclusivity

The development of a new drug involves different stages, during which a variety of data are produced to confirm its non-toxicity and efficacy. On the basis of test results data, national authorities can assess whether to grant marketing authorization for a new drug.

Under the TRIPS agreement, this clinical test data can be used by a country's drug regulatory authority as the basis to give safety or efficacy approval for generic drugs with similar characteristics, thus facilitating the dissemination and use of generic drugs. Indeed, if generic producers are obliged to repeat long and costly testing, competition will be reduced because of time delays and, more importantly, because some small and medium firms - especially local firms in developing countries like Tunisia - will lack the resources to undertake such testing<sup>54</sup>.

Data exclusivity is proposed by the EU within the framework of the DCFTA. The DCFTA states that public authorities are not allowed to grant generic manufacturers marketing authorization as long as the clinical test data is not explicitly approved by the owner<sup>55</sup>. This provision therefore prevents Tunisian regulatory authorities from relying on data submitted by the originator company. This applies even when the data are made public and accessible to everyone, meaning medicines that are off-patent may then become subject to exclusive rights<sup>56</sup>. Through these provisions on data exclusivity, drug companies are given additional protection, even if there are no patents on the product or after the patent expires.

Furthermore, the protection period granted for data is usually less than that granted under the patent for the medicine, but article 48 of the DCFTA proposal allows further extension of the protection period of data with another [X years], in case the marketing authorization holder obtains additional therapeutic indication(s). Such exclusivity is an expansion beyond TRIPS and was in fact debated and rejected during the TRIPS agreement negotiations, since the agreement does not create property rights over registration data.

Data exclusivity raises ethical concerns regarding the duplication of trials with already confirmed results<sup>57</sup>. Additionally, it blocks access to drugs at affordable costs as illustrated by the Jordanian experience with USA-Jordan FTA, where the drugs prices increased by 20% following the implementation of data exclusivity<sup>58</sup>.

Data exclusivity can also interfere with TRIPS flexibilities, mainly the compulsory license<sup>59</sup>, which is an authorization given by a national authority to a generic producer for the use and exploitation of a patented medicine without the consent of the patent holder (see Box 2). This authorization is usually granted under certain conditions such as a national emergency or anti-competitive practices. Yet, the compulsory license is only valid for the patent and does not cover the use of the protected data. The case of Romania reveals the obstacles to the effective use of compulsory licensing created by EU data exclusivity:

“In 2016, the government of Romania contemplated issuing a compulsory license for the hepatitis C medicine sofosbuvir, which, in Europe, was only available from the

<sup>52</sup> [European commission – Consultation \(2017\) Results of the stakeholder consultation, Online Public Consultation on a Deep and Comprehensive Free Trade Area with Tunisia](#) – Completed 22-02-2017.

<sup>53</sup> [Consultation sur le projet ALECA – Rapport conjoint du quatrième round de négociation sur un accord de libre-échange complet et approfondi \(ALECA\) entre la Tunisie et l'Union européenne Tunis, 29 avril - 3 mai 2019](#) – Published 05-06-2019.

<sup>54</sup> [Correa C. \(2002\) Protection of data submitted for the registration of pharmaceuticals. Implementing the standards of the TRIPS Agreement. Geneva: South Centre.](#)

<sup>55</sup> [Article 48, Protection of intellectual property. The texts proposed by the EU for a Deep and Comprehensive Free Trade Area \(DCFTA\) with Tunisia, Updated on 31 July 2018.](#)

<sup>56</sup> [Article 48, Protection of intellectual property. The texts proposed by the EU for a Deep and Comprehensive Free Trade Area \(DCFTA\) with Tunisia, Updated on 31 July 2018.](#)

<sup>57</sup> [Oxfam \(2007\) All costs, no benefits: how TRIPS-plus intellectual property rules in the US-Jordan FTA effect access to medicines. Oxfam Briefing Note, Mars 2007.](#)

<sup>58</sup> [Armouti, W., Nsouri Mohamed F.A., \(2016\) Data Exclusivity for Pharmaceuticals: Was It the Best Choice for Jordan Under the U.S.- Jordan Free Trade Agreement? Oregon Review of International Law, 17\(2\), pp.260-296.](#)

<sup>59</sup> ['t Hoen, E., Boulet, P., & Baker, B. K. \(2017\). Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation. Journal of pharmaceutical policy and practice, 10:19.](#)

originator company at a price of around 50.000 euro for a 12-week treatment. Since the registration of a generic version of sofosbuvir is not possible before the expiry of the data exclusivity in 2022, Romania, like any other EU Member State, cannot give effect to a compulsory license. Further, the EU market exclusivity for sofosbuvir expires at the earliest in 2024.<sup>60</sup>

In contrast, in August 2015, Tunisia was granted a voluntary license for producing the generic version of the Hepatitis C medicine by GILEAD. The Tunisian government and pharmaceutical producers were able to provide the drugs in public hospitals by mid-2016. Unlike Romania, Tunisia was able to issue a marketing authorization for the generic version of the medicine and to provide an abundant quantity of the drug in public facilities, which wouldn't have been possible if clinical and pre-clinical data were protected under the Tunisian patent law.

### 3. Trade Secret

Patents were designed with the intention of eventual knowledge dissemination, and consequently require the invention disclosure after the expiration of the protection period. When patents expire, generally after a 20-year period, then trade secrets can be reverse-engineered. This ensures that competition can eventually take place once the limits are reached. In contrast, trade secrets are not time limited and can remain protected as long as the information is held secret and their disclosure remains in the hands of the inventor. In addition, protecting undisclosed information costs little money and time to firms compared to patents as they require no registration nor government inspecting process. They only need measures to be taken within the firm that explicitly identify the subject matter as a secret. Thus, trade secrets can also be a substitute for patents<sup>61,62</sup>. Trade secrets apply to developed subject matters that cannot be considered as invention according to the patentability standards.

In the case of the EU's proposed DCFTA, trade secrets are also used to provide further protection beyond what is already ensured by the patent system. The EU provision on protecting undisclosed know-how and business information was introduced in the latest DCFTA proposal, published in July 2018. The initial proposal of 2016 left the section regarding trade secrets to be developed later at an advanced stage of negotiations. This delay can be explained by the absence of a unified European legal framework for protecting undisclosed data when the DCFTA negotiations first started with Tunisia. The European parliament only adopted the directive in June 2016<sup>63</sup>, after long rounds of discussions and negotiations on trade secrets.

To date, the latest European DCFTA proposal provides two provisions to protect trade secrets. The first one defines what can be considered as a trade secret in accordance to the points already set in article 39 of the TRIPS agreement. The second provision establishes the legal changes required to protect trade secrets.

Through these various mechanisms, the originator company can obtain endless benefits; at first with the patent system for a limited term and then, once that term expires, by using trade secrecy to block competition for the patented product. This leads to unlimited monopolies. But as mentioned before, monopolies limitation are important and fundamental goal of the intellectual property system because the public receives benefits from competition in the form of lower prices and increased access to medicines<sup>64</sup>.

In the case of the drugs industry, early stage formulas, measurements and manufacturing processes are usually not patentable and thus require other kinds of protection. Aside from the direct economic benefit generated from selling trade secrets, firms prefer relying on them as a complement and a supplement to the patent system<sup>65</sup>. The coordinated use of patents and trade secrets can help companies to keep secret necessary later-developed information about the product itself, the

<sup>60</sup> *ibid.*

<sup>61</sup> Price N.W., (2017) «Expired Patents, Trade Secrets, and Stymied Competition.» *Notre Dame L. Rev.* 92, no. 4, pp 1611-40.

<sup>62</sup> [WIPO - Patents or Trade Secrets?](#)

<sup>63</sup> *Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (Text with EEA relevance)*

<sup>64</sup> Price N.W., (2017) «Expired Patents, Trade Secrets, and Stymied Competition.» *Notre Dame L. Rev.* 92, no. 4, pp 1611-40.

<sup>65</sup> *European Commission. (2013). Study on Trade Secrets and confidential Business Information in the Internal Market*

<sup>66</sup> Price N.W., (2017) «Expired Patents, Trade Secrets, and Stymied Competition.» *Notre Dame L. Rev.* 92, no. 4, pp 1611-40.

<sup>67</sup> According to the US Food and Drugs Administration, "Biological products include a wide range of products such as vaccines, blood and blood components, allergenic, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources - human, animal, or microorganism - and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available."

<sup>68</sup> Price N.W., (2017) «Expired Patents, Trade Secrets, and Stymied Competition.» *Notre Dame L. Rev.* 92, no. 4, pp 1611-40.

required and bundled economic components needed for a meaningful marketing launch of a medicine, or later-developed information related to application instructions as required by consumers<sup>66</sup>.

These tactics are commonly witnessed with biological medicine<sup>67</sup>. Though trade secret cannot be used for small active molecule drugs, they can be employed for biologics, which are large molecule drugs. In this case, once the safety and efficacy of a biologic product is proven to the relevant authorities, generic products must be highly similar with the same clinical effect to the first one in order to not reproduce clinical tests. But trade secrecy can pertain to the way biologics are manufactured, even after the patents on the biologics have expired. Biologics products have a more complicated composition than small active molecule drugs and are the result of a complex manufacturing process. Generally speaking, scientific tools are not sufficient to capture the process through which biologics are produced in order to obtain generic versions. As seen before, if a generic producer is obliged to repeat long and costly testing, competition will be reduced because of time delays and, more importantly, because of a lack of resources to undertake such costly testing. This can be illustrated by reference to the medicine Premarin, which is a mixture of conjugated estrogens used for the treatment of menopause symptoms. The medicine was patented from 1940 to 1950 by Wyeth and has since been acquired by Pfizer. Premarin still lacks a generic competitor because they are unable to reverse-engineer it, more than seventy years after the drug was first marketed. This is due to the fact that the precise mixture of estrogens in Premarin is protected via trade secrets. The generic industry was unable to take the lead even after the patent expired because they have not been able to obtain the marketing authorization since their generic product is not similar enough to the one that obtained the patent due to their inability to reverse engineer it<sup>68</sup>.

In light of this analysis, the different national bodies responsible for DCFTA negotiations must be aware that not only drugs but also vaccines, blood and blood components, allergenic, somatic cells, gene therapy, tissues, recombinant therapeutic proteins and all biologics will all be impacted by the IP DCFTA proposal, specially by the provision concerning trade secrets.

Unlike its European counterpart, Tunisia does not possess a specific legal framework to protect undisclosed information. Yet, it provides the needed protection for trade secrecy in different legislation, including the labour code, the penal code and the competition law. The measures already in place to a good job of protecting trade secrets to support the viability and growth of trade while at the same time present no blockage to competition, especially with pharmaceutical products.

# Conclusion

As a WTO member state, Tunisia has no obligation to join any international agreement outside the ambit of TRIPS. Yet, with the DCFTA, Tunisia is drawn into a complex bilateral web of intellectual property standards, exceeding the TRIPS agreement obligations, and preventing it from using TRIPS flexibilities.

Increasingly, Tunisian authorities are going to find themselves constrained by international and bilateral agreements, unable to fulfil their obligations to their citizens- in this case, to provide them with access to essential, life-saving medicines. If the DCFTA provisions discussed in this report are applied in the current Tunisian context, it is certainly they will negatively impact both the cost of patented medicines, as well as the long-term viability of generic industries, jeopardizing access to medicines at an affordable price.

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