Data Exclusivity under Moroccan Law

Data exclusivity provisions refer to a practice whereby, for a fixed period of time, national drug regulatory authorities prevent and block the registration files of an originator to be used to register a therapeutically equivalent generic version of that medicine without obtaining the consent of the patent holder unless the generic manufacturer actually reconducts the clinical trials. Data exclusivity is a completely separate form of protection from patents. The TRIPS Agreement does not require specifically this form of protection but rather refers to the protection of "undisclosed test or other data" against "unfair commercial use" and "disclosure" as stated Article 39.3 of the TRIPS Agreement.

Morocco implemented the protection of Data of exclusivity due to the inclusion of this under the US-Morocco FTA signed in 2006. Based on this, Article 15.10.1 of the FTA states:

> ARTICLE 15.10: MEASURES RELATED TO CERTAIN REGULATED PRODUCTS
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> 1. If a 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, the Party shall not permit third persons not having the consent of the person providing the information to market a product on the basis of the approval granted to the person submitting that information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party's territory. For purposes of this paragraph, a new product is one that contains a new chemical entity that has not been previously approved in the Party's territory.
>
> 2. If a Party requires the submission of (a) new clinical information that is essential to the approval of a pharmaceutical product (other than information related to bioequivalency), or (b) evidence of prior approval of the product in another territory that requires such new information, the Party shall not permit third persons not having the consent of the person providing the information to market a pharmaceutical product on the basis of such new information or the approval granted to the person submitting such information for at least three years from the date of approval in the Party. A Party may limit such protection to new clinical information the origination of which involves considerable effort.

In brief, the above provision requires the implementation of data exclusivity protection regime in the country by requiring:

1. Grant of five years exclusivity protection over test data and 2. A further three years exclusivity grant for "new clinical information" even if a drug is

not patented in Morocco.

The impact of this on access to generic medicines in the country may be summarised as follows:[1]

1. The prevention of generic manufacturers from obtaining the data needed to make generic versions of new medicines in the country.
2. It would create another form of legal protection even if no patent exists in the country.
3. It would also prevent the authorities from utilizing compulsory licensing in case of the existing of a data exclusivity protection term.

- Options for Mitigating the Negative Impact of Data Exclusivity:

Many countries undertook several steps to reform their protection regimes in order to mitigate the negative impact of extended IP TRIPS-Plus and data exclusivity rules following the signing of an FTA. This part will look at a couple of cases which may provide useful lessons in this context to Morrocco. Both countries signed similar FTAs with the USA.

First: The case of Chile: Chile signed an FTA with the US in 2006 with included data protection requirements.[2] Following extensive national public debate, Chile reformed its law by limiting availability of data protection under its national law to those pharmaceutical products that have been marketed in the national territory in the year after the grant of marketing approval and therefore if the drug was not marketed within a year, the test data submitted for approval purposes will not be protected. The rationale behind such a requirement is to encourage early registration of drugs after first registration abroad, so that the period of protection for the pharmaceutical test data starts early. In addition, the law excluded several elements from the scope of protection (as in case of issuance of compulsory license and anti-competitive practises). Accordingly, Article 91 of the Chilean law states:

> The protection of this Paragraph shall not apply when:
>
> (a) The owner of the test data referred to in Article 89 has engaged in forms of conduct or practices declared as contrary to free competition indirect relation to the use or exploitation of that information, according to the final decision of the free competition court.

[1] The negative impact of data exclusivity on access to generic medicines has been documented by many studies around the globe, for example see Gargi Chakrabarti, *Need of Data Exclusivity: Impact on Access to Medicine*,

19 J. INTELL. PROP. RIGHTS 325 (2014) and Nusaraporn Kessomboon et al., *Impact on Access to Medicines from Trips-Plus: A Case Study of Thai-US FTA*, 41 SOUTHEAST ASIAN J. TROPICAL MED. &PUB. HEALTH 667, 674 (2010).

[2] Article of the FTA states

(b) For reasons of public health, national security, non-commercial public use, national emergency or other circumstances of extreme urgency declared by the competent authority, ending the protection referred to in Article 89 shall be justified.
(c) The pharmaceutical or chemical-agricultural product is the subject of a compulsory license, according to what is established in this Law.
(d) The pharmaceutical or chemical-agricultural product has not been marketed in the national territory after 12 months from the health certificate or clearance granted in Chile.
(e) The pharmaceutical or chemical-agricultural product has a health certificate or clearance abroad that has been in force for over 12 months.

Second: The case of Jordan: Jordan was the first Arab country to sign an FTA with the US back in 2002.[3] The FTA was also one of the first to attract attention due to the TRIPS-plus conditions stated. Data exclusivity clauses included under the agreement resulted in negative impact on access to medicines in the country as documented by Oxfam study in 2007.[4]

The US-Jordan FTA data exclusivity requirements are relatively milder than those stated under the US-Morrocco FTA. For instance, while the US-Morocco FTA requires protection of data exclusivity for five years exclusivity over test data and a further three years exclusivity for "new clinical information", the US-Jordan FTA requires only 3 years protection for "new chemical entities" only.

Despite the above and following an active public discourse between various stakeholders in Jordan, the laws were amended in 2015 in order to reduce the negative impact of the FTA on the pharmaceutical sector with relation to data exclusivity requirements. Some of these reforms followed those justifications explained in the Chilean case above. As such, several amendments were introduced in 2015 to address the following issues:

1. Narrowly defining New Chemical Entities (NCEs) for the registration purposes:

The US-Jordan FTA stipulates that the protection for "new chemical entities" shall include 1) protection for new uses for old chemical entities, 2) for a period of three years. However, beyond this, the FTA does not define what NCEs are for

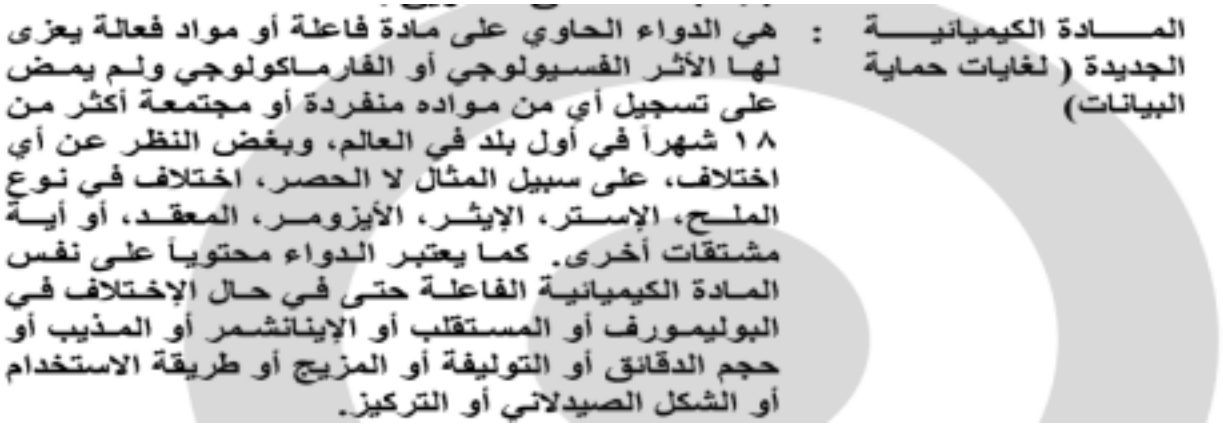
[3] Article 4.22 of the FTA states:

Measures Related to Certain Regulated Products

22. Pursuant to Article 39.3 of TRIPS, each Party, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products that utilize new chemical entities,[3] the submission of undisclosed test or other data, or evidence of approval in another country,[3] the origination of which involves a considerable effort, shall protect such information against unfair commercial use. In addition, each Party shall protect such information against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the information is protected against unfair commercial use.

[4] See Oxfam, *All Costs, No Benefits: How TRIPS-Plus Intellectual Property Rules in the US-Jordan FTA Affect Access to Medicines* 7 (Oxfam Int'l, Briefing Paper No. 102, 2007).

the purpose of the law or registration. The below definition was introduced in the 2015 Registration of Medicines Conditions (hereinafter the Registration Conditions) which limits protection to those NCEs which have not been registered for more than *18 months* in the *first* country of registration anywhere in the world. Based on this, to be granted data exclusivity protection, originators should register the medicines in Jordan within a maximum period of 18 months from the registration in their origin country. If they go beyond this period, they would not be granted any protection. The clause below including the definition as per the Registration Conditions.



المـــــادة الكيميائيـــــة الجديدة (لغايات حماية البيانات) : هي الدواء الحاوي على مادة فاعلة أو مواد فعالة يعزى لها الأثر الفسيولوجي أو الفارماكولوجي ولم يمض على تسجيل أي من مواده منفردة أو مجتمعة أكثر من ١٨ شهراً في أول بلد في العالم، وبغض النظر عن أي اختلاف، على سبيل المثال لا الحصر، اختلاف في نوع الملح، الإستر، الإيثر، الأيزومر، المعقد، أو أية مشتقات أخرى. كما يعتبر الدواء محتوياً على نفس المادة الكيميائية الفاعلة حتى في حال الإختلاف في البوليمورف أو المستقلب أو الإينانشمر أو المذيب أو حجم الدقائق أو التوليفة أو المزيج أو طريقة الاستخدام أو الشكل الصيدلاني أو التركيز.

2. <u>Registration Conditions</u>

The 2015 Registration Conditions introduces some important limitations on data exclusivity protection including the stipulation that data exclusivity applies only to "new chemical entities" as per the below article. Based on this, new medicines which are available in the market that are modifications of known substances would be excluded from registration.

Moreover, the Article also states that generic manufacturers can now apply for registration of their generics during the last year of data exclusivity protection (I,e the 4rth year) as the process of approval may take up to 12 months in certain cases. This has the impact of reducing the time of entry of generics into the market. This will almost have the same impact as the Bolar exemption.

ب- يقدم طلب تسجيل الدواء المثيل لدواء محمية بياناته (الحاوي على مادة كيميائية جديدة) و ذلك في السنة الأخيرة قبل انتهاء الحماية كحد أقصى من قبل الصيدلي المسؤول في المستودع / مصنع الأدوية المحلي و يرفق به الملف المكتمل الوثائق حسب المتطلبات الواردة في الملحق رقم (١) و يعطى تسلسلا ضمن ملفات الأدوية التي لها مثيل مسجل محمية بياناته.

In addition, the Registration Conditions contain some situations where the importation, distribution, suspension, cancellation or recollection of the medicines may take place. Examples of these situations would be applicable in cases of proven non-efficiency/efficacy of the medicine, its suspension in its country of origin, if registration was made based on incorrect information.

Conclusions:

The cases of Chile and Jordan provide interesting studies to be considered by Morrocco for several reasons. This is due to the fact that both countries have signed similar FTAs with the US around the same period of time (Jordan in 2002 and Chile in 2006). The FTAs included similar data exclusivity requirements somehow, and more importantly both countries have introduced reforms to their national data exclusivity regimes since few years.

The current provision regulating the situation in Morocco could be modified/updated to take note of the above two cases presented.[5] Notably, the EU have also introduced new reforms in 2023 to address the issue of data exclusivity. One of these important reforms would be to suspend data and market exclusivity in case of issuance of compulsory license.[6]

[5] Article 4 of the decree n°2-14-841) states:
المادة 4: عندما يتم منح الترخيص االولي للتسويق في المغرب لدواء يحتوي على) مكون أو عضو (جديد ذو هيكل كيميائي محدد، باستثناء المواد المساعدة واألصباغ ومعدالت الطعم والمثبتات والمواد المخففة والمواد الحافظة، ال يمكن لطرف ثالث طلب ترخيص التسويق لدواء مماثل واإلشارة، دون موافقة صاحب الترخيص االولي، إلى البيانات التي قدمها هذا الشخص والتي سمحت بتحديد سالمة وفعالية الدواء ال ُمر َّخص به. تطبق هذه القيود لمدة خمس سنوات من تاريخ الحصول على الترخيص االولي للتسويق في المغرب.

[6] See Health Policy Watch, European Commission Finally Releases Pharma Law Reforms, Proposing Cuts to Market Exclusivity for New Drugs, 26 April 2023 at https://healthpolicy-watch.news/european-commission finally-releases-pharma-law-reforms-proposing-cuts-to-market-exclusivity-for-new-drugs/