Data Exclusivity for Pharmaceutical Drugs in Turkey

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In Turkey, a process called an "abbreviated application" allows generic drug producers to apply for marketing authorization without submitting information about tests and clinical trials, if a data exclusivity period does not exist, in certain circumstances. Data exclusivity enables drug producers to keep their test and clinical trial data confidential, for up to six years. The exclusivity period starts from the date that a pharmaceutical product first receives marketing authorization in a country which is a member of the European Union-Turkey Customs Union (sub-paragraph of Article 9 of the Regulation on Licensing of Human Medicinal Products dated January 19, 2005 numbered 25705 ("**Regulation**")). During the exclusivity period, generic drug producers cannot refer to the information gathered by the original marketing authorization holder.

The Concept Of Data Exclusivity - Legal Protection For Commercial Investment

The primary intellectual property rights relevant to pharmaceutical companies are trademark, patent, trade secrets and data exclusivity. Since R&D activities in this industry are greatly complicated, patent protection alone is inadequate to effectively protect and safeguard the resulting intellectual property. Therefore, one of the most important rights in this area is data exclusivity, which has a direct effect on the ability to market a pharmaceutical product.

In Turkey, no pharmaceutical product for human use may be marketed unless it is authorized by the Ministry of Health ("**MoH**"). In granting a marketing authorization, the MoH requires drug producers to submit the results of their pharmaceutical products' safety and efficacy tests, along with other documents regarding the product. In effect, drug producers must invent and develop a pharmaceutical drug product through intensive and time consuming studies, then provide the results of the toxicological and pharmacological tests and clinical trials to the MoH in order to obtain a marketing authorization to commercially exploit their product. Here data exclusivity provides original drug producers with protection for the information gathered from their clinical trials and studies. During the data exclusivity period, generic drug producers cannot use or rely on that data in order to obtain marketing authorization from the MoH for the same drug.

Parties in favor of data exclusivity argue that generating the data required to obtain marketing approval for an original drug requires a significant investment of time, expertise, resources and money. It would arguably be unfair and unjust to allowing generic companies to produce generic versions of patented drugs without incurring similar expenditure or investment. Therefore, it is argued that manufacturers of original drugs should be encouraged and rewarded. Under this argument, data exclusivity represents legislative protection for the complex, time consuming and expensive R&D exercises which original manufacturers undertake. The protection exists for a limited time, before competitors are permitted to use this data to obtain approval of generic alternatives.

Counter to this, many generic drug manufacturers and public interest groups maintain a stance against data exclusivity. Their primary argument is that data exclusivity, even for a finite time period, negatively impacts access and affordability of life-saving drugs, particularly in the third world and developing economies. They state that rigidly protecting the rights of the original drug producer, effectively excluding generic drug producers from the market, could cause an unbalanced market structure to develop. In practice, generic drug manufacturers generally have less financial capability to conduct these expensive and time consuming tests. Even if generic drug manufacturers have

the financial capacity to conduct such tests, doing so will inevitably increase the downstream prices of the generic drugs. Ethical questions inevitably arise during clinical processes due to their frequent involvement of animals and volunteer patients as test subjects to determine a product's efficacy, quality and biosafety. Generic drug producers argue that it is wasteful and unethical to repeat clinical trials simply in order to gain the MoH's marketing approval.

Duration Of Data Exclusivity

When the data exclusivity period expires, generic drug producers are allowed to enter the market. Therefore, the duration of the exclusivity period is of key importance to all parties involved. The data exclusivity period varies from country to country, ranging from five to ten years.

As an example, European Union legislation grants a data exclusivity period which lasts eight years, plus an additional two years (and may be extended for another year). Turkish legislation has not established a data exclusivity period akin to the period regulated under the European Union legislation. According to Article 9/a(3) of the Regulation, original pharmaceutical products which have been licensed in a Customs Union Member State are subject to a data exclusivity period of six years. This term of six years starts from the "first" licensing of such original product in any of the Customs Union Member State. If a Turkish patent exists, the data exclusivity will end when the patent expires, even if this is earlier than six years.

Basically, the period of data exclusivity depends on the term of any Turkish patent which covers the active substance of the biological reference product. Therefore, to determine the data exclusivity period in Turkey, it is important to know whether patent protection exists or not. For example, a pharmaceutical product (A) receives a marketing authorization in a country which is a member of the European Union-Turkey Customs Union in September 2013 and this is the first authorization date in any of the member States to the Customs Union. Accordingly, the data exclusivity will start from September 2013 and remain for six years. However, if there is a Turkish patent covering (A) which expires in August 2014, then the data exclusivity for (A) would only exist until August 2014, when the Turkish patent expires.

Patent Protection For Pharmaceutical Drug Products - A Different Type Of Protection To Data Exclusivity

A pharmaceutical drug product can hold both data exclusivity and patent protection, but each provides a different type of protection. The main purpose of data exclusivity is maintaining confidentiality of data and enabling the original drug producers to keep competitors away from its market share. Patent protection allows the right holders to enjoy the exclusive use of their patented information and enables the right holders to prevent other parties from selling, importing and exporting the patented products. Data exclusivity is especially vital where no patent protection exists for a pharmaceutical drug product.

For products protected by a patent in the European Union, it is possible to extend the monopoly period of a product beyond the expiry of the patent registration. The practice is called the Supplementary Protection Certificate for Medicinal Products (SPC) and was introduced on 2 January 1993 by 1768/92 EEC Directive. In Turkey, patent protection rights terminate completely on the expiry of the patent protection term. Turkish law does not contain a mechanism to extend the protection period, similar to the supplementary protection certificate system which exists in the European Union. As a result, Turkish drug producers may only benefit from patent protection for the period defined by the patent term.

Some companies prefer to protect their innovative work by closely maintaining its confidentiality, rather than register the drug product as a patent where the whole invention is publically disclosed. The downside of this approach is that if another party independently develops the same information, data, process etc., then there would be no violation of the earlier party's legal rights to that information. If the earlier party holds a registered patent, the later party would be in violation of this intellectual property right.

Patent Protection Laws Are Insufficient On Their Own To Establish A Data Exclusivity Framework In Turkey

Patent protection generally and mainly is harmonized at international level by the Paris Convention (1967) on the protection of Industrial Property and then Trade-Related Aspects of Intellectual Property Rights - TRIPS agreement ("**TRIPS**") annexed to Agreement Establishing the World Trade Organization. The Grand National Assembly of Turkey ratified the main agreement and its annex TRIPS in January 26, 1995. In order to come into compliance with these agreements, Turkey has taken steps in the Intellectual Property arena.

Turkish law contained no patent protection for pharmaceuticals until 1995 when the Decree Law No. 551 concerning the Protection of Patent Rights was enacted. Article 83/3 of the Patent Decree Law provides protection for undisclosed information, but does not state a specific time period for exclusivity:

> *"Where an application for patent has been filed for pharmaceutical or veterinary products/drugs and for chemicals destined to agriculture, the authorities issuing authorizations/licenses for the manufacture and sale of such products and requesting for this purpose information and test results, that were not disclosed to the public and the realization and accumulation of which requires considerable expenses and efforts, shall keep such information and test results secret/confidential. The authority asking for such information and test results shall take the necessary measures to prevent unjustified/illegitimate use thereof".*

Article 83/3 of the Patent Decree Law is analogous to Article 39/3 of the international TRIPS Agreement. However, since Article 83/3 of the Patent Decree Law does not state a time period, on its own, this Article is arguably insufficient to explicitly establish a data exclusivity framework in Turkey. Despite this, pharmaceutical companies were using the TRIPS Agreement and local Patent Decree Law as the basis of their arguments in favor of data exclusivity periods existing in Turkey.

The Regulation On Licensing Of Human Medicinal Products Clearly Established A Data Exclusivity Framework In 2005

The situation in Turkey was clarified in 2005 when the Regulation on Licensing of Human Medicinal Products was introduced, ten years after the Patent Decree Law. Article 9 of the Regulation clearly provides data exclusivity protection for a specific six-year period. Thus, a data exclusivity framework was explicitly introduced to Turkish legislation.

The Regulation introduces the data exclusivity framework during its discussion of the "Abbreviated Application" procedure. This procedure allows generic drug producers to obtain marketing authorization without having to submit the results of toxicological and pharmacological tests or clinical trials in certain circumstances.

According to Article 9/a of the Regulation, applicants can obtain a marketing authorization from the MoH without submitting pre-clinical tests or clinical trials if:

1. The product is similar in principle to a pharmaceutical product which has previously been authorized in Turkey and the marketing authorization holder of the original product gives its consent for the applicant to use this information for the purpose of obtaining a marketing authorization (Article 9/a(1) of the Regulation), or
2. The components of the pharmaceutical product have reasonable activity and admissible reliability settled in medical utilization (Article 9/a(2) of the Regulation), or
3. The data exclusivity period for the original pharmaceutical product, which is similar in principle to the generic product, has expired (Article 9/a(3) of the Regulation).

Nevertheless, for any product that provides different therapeutic indications, usage and doses from a product that has already been launched to market, it is necessary to submit clinical trial results and other toxicological and

pharmacologic trial results.

In practice, without having any legal grounds, the MoH allows abbreviated marketing authorization applications to be made within the data exclusivity protection period but withholds the marketing authorization until the original product's data exclusivity period expires. If the MoH only accepted marketing authorization applications after the six year marketing authorization period expired, no generic product would be launched to market until the end of MoH's evaluation of the abbreviated marketing authorization applications. If the MoH took this approach, it would in effect allow an extension of the data exclusivity protection period, beyond the six years stated in the Regulation. Accordingly, by accepting abbreviated marketing authorization applications within the data exclusivity protection period, the MoH shows that it does not intend the original product to benefit from data exclusivity for more than the strict six year period.

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