MOROĞLU ARSEVEN

THE BOLAR EXEMPTION AND DATA EXCLUSIVITY: HOW THEY APPLY IN TURKEY

In Turkey, pharmaceutical products for human use cannot be marketed unless they are authorized by the Ministry of Health ("MoH"). In order to grant pharmaceutical license and marketing authorization, MoH requires pharmaceutical companies to submit the results of their pharmaceuticals' safety and efficacy tests, along with other documents regarding the product.

In effect, pharmaceutical companies must invent and develop a pharmaceutical product through intensive and time-consuming research and development activities, then provide the results of the toxicological and pharmacological tests and clinical trials to MoH in order to commercially exploit their product. This is a long and costly process for introducing new or more effective treatments for patients.

Generic pharmaceutical companies, on the other hand, may submit abridged applications to MoH. If a data exclusivity period does not exist, they can apply for marketing authorization by referring to the original drug's data, without submitting tests and clinical trials data. **Provided that they prove the efficacy and safety of their pharmaceutical product, the abridged application process allows generic companies to obtain the same result as a drug's inventor without going through long and costly processes.** This can enhance competition in the market by offering more choice and by lowering drug prices.

However, there is a balance that needs to be struck by protecting the investments of drug originators. This protection is provided through intellectual property rights and the concept of data exclusivity in the regularity field as well, which enables pharmaceutical companies to keep their valuable test and clinical trial data confidential, for a certain limited time period.

Data Exclusivity in Turkey

The concept of data exclusivity arose in Turkish Law in 2005, with the introduction of the Regulation on Licensing of Human Medicinal Products (no: 25705). This regulation was updated in December 2021, with the Regulation on Licensing of Medicinal Products for Human Use published in Official Gazette no: 31686 **("Pharma Regulation").**

According to Article 9 of the Pharma Regulation:

Data exclusivity shall apply for the reference medicinal products, which shall be **licensed for the first time since 1/1/2005** in one of the countries within the Customs Union Area.

The data exclusivity period shall be six years, commencing as of the first licensing date in the Customs Union Area; however, **this period of six years is limited with the patent term**, and therefore the patent term cannot be extended by data exclusivity.

There is **no formal requirement or precondition** for obtaining data exclusivity rights.

The **protection is automatically** put in place when the marketing authorization is issued.

Data exclusivity rights of the original product's license holder is taken into **consideration ex-officio by the Agency**.

Data exclusivity provides originators with protection for the information **gathered from their clinical trials and studies**.

During the data exclusivity period, **generic companies cannot use or rely** on that data in order to obtain marketing authorization from the MoH.

Data exclusivity as an intellectual property right stands independently from patent law and gives the data holder certain exclusivity rights enabling them to keep competitors from the market for a limited period of time.

However, Bolar Exemption brings a limit to the applicability of data exclusivity.

Bolar Exemption in Turkish Law

According to Article 85/3-c of the Industrial Property Law numbered 6769, **trial practices, which include tests and experiments necessary to establish a patent, are excluded from patent protection**. This exemption allows pharmaceutical companies to use the patent for clinical trials, tests, and license applications for generic drugs before the expiration of the patent protection period.

This allows generic products to be released to the market immediately after protection for the patented pharmaceutical expires. Allowing the tests and trials to start and run only after the expiration of patent protection **would artificially extend the 20-year patent protection period, because the required tests and trials take a long time.** The Bolar Exemption, therefore, enables the release of generic products to the market as early as possible and enables more seamless public access to medicine.

The Practice in Turkey

The Bolar Exemption is widely accepted and implemented in Turkey. Both the MoH and the Turkish courts do not view clinical tests and trials, abridged license application and granting of licenses as patent infringement under Bolar Exemption. According to established court precedent and MoH practice, filing an abridged license application to obtain a marketing authorization for a pharmaceutical product does not violate data exclusivity either.

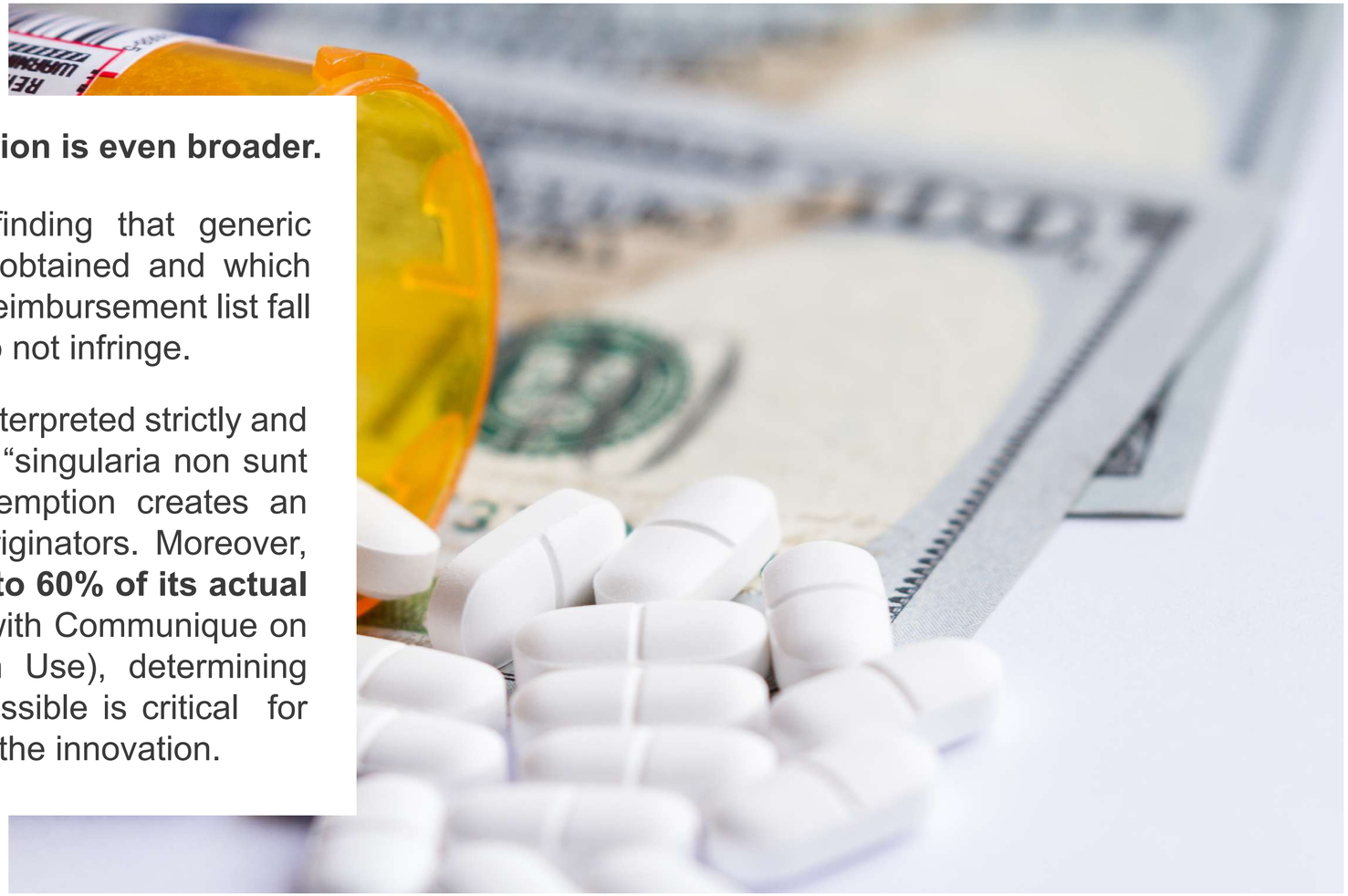
In practice, MoH allows **abridged license applications referring to an original product** that is still within the data exclusivity protection period. In such cases, **sales permission is withheld until the end of the data exclusivity period of the original product.** If the MoH only accepts marketing authorization applications after the expiration of the six-year data exclusivity period, the process for a marketing authorization application and the MoH's period for evaluating the application would start after six years.

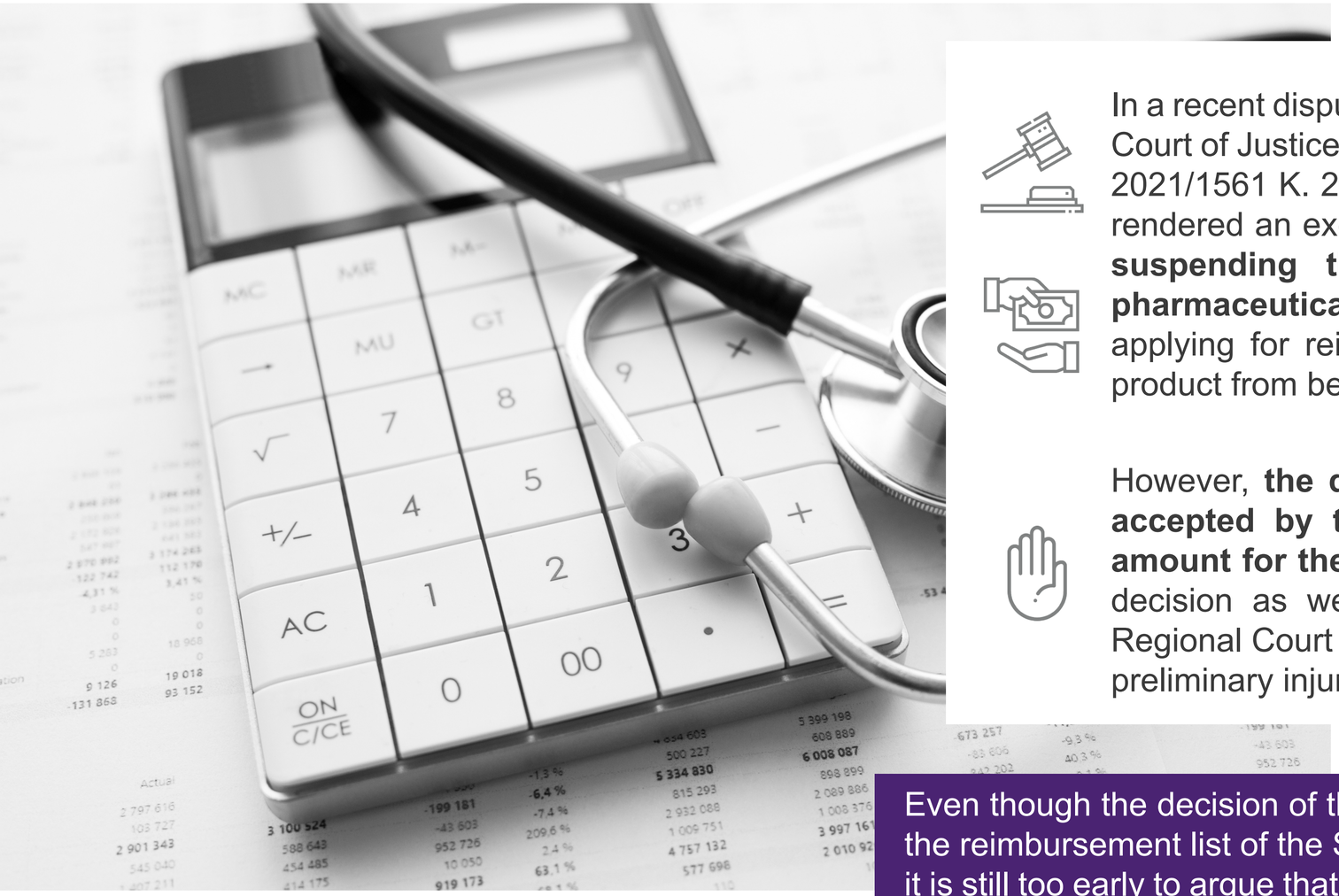
According to MoH, such practice would have resulted with the data exclusivity period being practically longer than the six years as foreseen in the Pharma Regulation. Even though there have been unfair competition actions brought by data holders based on their data exclusivity rights, the Court of Appeal has stated numerous times that when generic companies apply for authorization referring to the original right holder's data during the data exclusivity period, it does not constitute unfair competition and falls within the scope of Bolar Exemption. This helps ensure a balance of rights and interests between reference drug producers and generic drug companies.

In some cases, the interpretation of Bolar Exemption is even broader.

For example, there are court decisions finding that generic products for which price confirmation was obtained and which were listed on the Social Security Institution reimbursement list fall under the Bolar Exemption—and therefore do not infringe.

Since Bolar Exemption is an exception, it should be interpreted strictly and narrowly according to the general interpretation rule “singularia non sunt extenda”. Such a wide interpretation of Bolar Exemption creates an obstacle for the enforcement of patent rights for originators. Moreover, since **the price of the original product decreases to 60% of its actual price** once the generic product is launched (in line with Communique on the Pricing of the Medicinal Products for Human Use), determining whether there is patent infringement as early as possible is critical for originators to maintain their interest in contributing to the innovation.





In a recent dispute subject to the decision rendered by Istanbul Regional Court of Justice 16th Civil Chamber in the file with the docket number E. 2021/1561 K. 2021/1782 dated 20 October 2021, the Istanbul IP Court rendered an exceptional and promising preliminary injunction decision, **suspending the price cut decision issued for the original pharmaceutical by MoH.** This prevented the generic company from applying for reimbursement before the SSI and stopped the generic product from being listed in the reimbursement list of the SSI.

However, **the defendant's objection to the decision was partially accepted by the first instance court by raising the guarantee amount for the preliminary injunction**. The defendant appealed this decision as well, and their appeal was also accepted by Istanbul Regional Court of Justice, which is the highest authority to examine the preliminary injunction requests.

Even though the decision of the court to prevent the generic drug from being listed in the reimbursement list of the SSI is promising for the enforcement of pharma patents, it is still too early to argue that broad interpretations of Bolar Exemption have changed in Turkey, which continues to create challenges for originators.

AUTHORS

Ezgi Baklacı Gülkokar, LL.M.
Partner

Merve Altınay Öztekin
Senior Associate