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Determination of evidence in disputes over pharmaceutical patents

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Introduction

The determination of evidence, one of the most important temporary legal protection measures regulated in Turkish law, is an institution that ensures the protection of evidence which will assist in proving the matter in question. Considering that the adversarial trial process is adopted in Turkish civil procedure law, the significance of the rights holder being able to have the evidence that will help them prove themselves effectively determined is clear. However, in disputes relating to pharmaceutical patents, the determination of evidence institution is also a prerequisite in order to benefit from a preliminary injunction, which is another interim measure institution.

Provisions for determination of evidence

The general provision regarding the determination of evidence institution is included in article 400 of the Code of Civil Procedure No. 6100 (CCP). In this context, the determination of evidence can be conducted to determine a fact that has not yet been examined in a case or that will be asserted in a case to be filed in the future. Further, the legal benefit of the determination of evidence is acknowledged – there is the possibility that evidence will be lost or will be significantly more difficult to assert if not determined immediately.

However, article 150 / (3) of the Industrial Property Law No. 6769 (IPL) states that, for the determination of evidence before the rights holder files for indemnity based on a violation of their intellectual property rights, the rights holder may request the court to order the indemnity obligee to submit documents regarding the unjustified and unauthorised use of the intellectual property right. In parallel, pursuant to the Agreement on Trade-Related Aspects of Intellectual Property Rights, which serves as a law pursuant to article 90 of the Constitution, judicial authorities have the power to order immediate and effective interim measures to protect the evidence related to an alleged infringement.

Regulation of evidence

Considering the importance of the determination of evidence in industrial property rights and related cases, it has become necessary for the legislature to regulate the determination of evidence institution separately in indemnity cases, both in international conventions regarding the determination of evidence, and in special laws.

This requirement is at a different level for drug patent holders. Drug patent holders can only actively benefit for seven to 10 years from patent rights, which grant an absolute right for 20 years from the date of application. This is due to the long research and development period and licensing processes required for their original drugs, which enable them to benefit from their patents economically. Moreover, if a product that infringes the patent is introduced to the market, the price of the original drug of the patent holder is automatically reduced by 40% and, following this price decrease, rapid market loss begins with the introduction of generic products with a much higher price competitive margin.

For drug patent holders to benefit from their limited-term patent rights in accordance with the law, it is essential that they prevent the infringing product from being released to the market by ordering a preliminary injunction before its release to the market. Article 159 of the IPL, which regulates the conditions of preliminary injunction requests, states that to ensure an effective verdict, individuals with the right to file a lawsuit may request the court to order a preliminary injunction where it is proven that the use subject to the lawsuit is taking place within the country in a way that constitutes an infringement of their industrial property rights or that serious and effective studies have been carried out for the realisation of the infringement.

Accessing information

However, most of the time, it is not possible to access licence dossiers about an infringing drug without a court decision, which is the main evidence upon which the patent holder can rely to prove that the preliminary injunction conditions have been met. It is not possible for a patent holder to access evidence that is not on the market yet – namely, the infringing drug – and thus they cannot prove their claims via reverse engineering tests before the infringing drugs are actually on the market. Moreover, even after the infringing drug is put on the market, without a court decision, the patent holder cannot access the registration dossier of the relevant drug, which is submitted to the Ministry of Health to obtain a licence and which contains information on patent infringement.

While obtaining proof is difficult for drug patent holders under the IPL, the rights holder is required to prove that their industrial property rights will be infringed upon or that serious and effective studies have been carried out for the realisation of the infringement, in order to grant the preliminary injunction request. Thus, the importance of an evidence determination decision ordered by the court is evident. Without a decision to determine the evidence, it will not be possible for a drug patent holder to prove that the conditions for granting preliminary injunction in article 159 of the IPL are met in order to benefit from a preliminary injunction institution.

On the other hand, it is evident that different courts have different approaches to the determination of evidence. One of the main problems is manifested in tying the exercise of the right to determination of evidence to the conditions for issuing a preliminary injunction. However, as has been held by other courts, the determination of evidence is a first step in terms of determining the right and rightfulness and it should be evaluated independently of the exceptional circumstances that prevent the assertion of patent rights.

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