Innovator companies seek to protect themselves against generic companies

Özge Atılgan Karakulak and **Aysel Korkmaz Yatkın** of **Gün + Partners** examine the rules around abridged marketing authorisation information sought by innovator companies wishing to avoid patent infringement from generic companies

In order to contribute to human health, innovative pharmaceutical companies carry out studies that take many years and require huge amounts of investment and research, and as a result, they obtain patent protection for their inventions for a limited period of time. It is very important that the patent rights, which are limited only for a certain period of time, can be used and protected effectively. Applying for abridged marketing authorisation (MA) by referencing the original medicine protected by the patent holder's patent, data and other rights belonging to generic companies can create a situation where innovator companies face the danger of patent infringement. Article 85/2-c of the Industrial Property Law No. 6769 excludes any experimental acts involving the invention subject of a patent, including obtaining MA for medicines and tests and experiments required for it. With this provision, also known as the Bolar exemption, generic companies can obtain MA by applying for abridged MA before the patent protection period expires by referencing the original patent-protected medicine's MA dossiers belonging to the inventor company.

In circumstances where original medicines subject to a patent are referenced, it is often observed that activities that may result in infringement of patent rights of the innovator company are continued after the MA is obtained by the generic company. They apply for price, sales permit and even the reimbursement list of the SSI for the generic medicine after the registration is completed. It is very important that these developments are discovered by innovator companies without delay. There is no doubt that if this information is not discovered by the innovator company in time, the failure to take the necessary legal action will lead to irreparable damages. In this respect, the provision of timely information to innovator companies is essential for the effective protection of patent rights.

Özge Atılgan Karakulak

Özge Atılgan Karakulak has been with Gün + Partners since 2005 and a partner since 2013. She is chair of the firm's life sciences industry and competition practices and co-chair of the intellectual property practice.

With the combination of Özge's advisory and litigation expertise and in-depth knowledge of the life sciences sector, she advises clients across all phases of the business cycle of life science products. Özge has acted on behalf of originators in numerous complex patent infringement and validity actions in the pharmaceutical industry, and she was involved in the first ever pharmaceutical data exclusivity actions in Turkey.

Aysel Korkmaz Yatkın

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With almost 12-years of experience in patents, she has been providing consultancy on all matters related to patent law and has been leading numerous patent actions. With vast advisory and litigation expertise, particularly in relation to protection of patent rights, she also represents various pharmaceutical companies before the Ministry of Health in relation to regulatory matters and gives support to these companies on regulatory matters during the audits conducted.

Information on abridged MA applications

In light of this information, the most important information in terms of pharmaceutical patents is whether there is an abridged MA application before the Ministry of Health (MoH) for the original medicine under patent protection, so that it can observe whether there is a patent infringe-ment situation and take action for protection when necessary. Since this information is not available to the public, it may be possible to monitor whether these rights have been infringed by filing an action based on the information of the applicant obtained from the ad-ministration or to request the cease of the infringement from the addressee of the information. In particular, who and/or by whom the application was made, the time, the form of the product and the dosage information are known in advance via information request applications made by innovator companies.

In this regard, the administrative body from which patentees may seek legal remedy is the Turkish Medicines and Medical Devices Agency (TMMDA). Patentees can approach this entity about the possible existence of abridged MA applications made before the MoH by generic companies, the determination of any breach or infringement or threat by these applications and the required legal action.

Prior to 2007, requests for similar information by the originator pharmaceutical companies from the MoH, which was the sole authority in the relevant period, were rejected, stating that the requested information is confidential.

Upon rejection of these information requests from the MoH, in the two lawsuits filed before the Council of State, the Council of State annulled individual decisions and implementation of the MoH's decision.

Within this scope, in summary, in the decision of the 10th Cham-ber of State Council numbered 2004/13009 E. 2007/3200 K. the plaintiffs claimed that pursuant to Article 2 of the Attorney's Law No. 1136, state organisations and institutions must assist attorneys in the course of fulfilment of their duties. Save for the special provisions stated in the law, these organisations are obliged to present for the examination of the attorneys the information and documents required by them. They also stated that in order to determine whether their client's rights had been violated and to effectively protect these rights, abbreviated MA application dossiers must be examined by the lawyer.

Additionally, they asserted that pursuant to Article 39 of TRIPS, the rule concerning the confidential information provided to the ministry during the MA application is intended to protect information that is not known by individuals dealing with such information or that cannot be easily obtained by such individuals, which is confidential, not disclosed, not subject to sharing and which has commercial value because of its confidential nature. They stated that the pharmacological and toxicological test results and clinical trial results required to be presented during the original medicine MA applications are therefore confidential, whereas in the abbreviated MA applications for generic medicines, no scientific data or commercial information should be kept confidential as the original product's information is referenced.

Therefore, based on all these reasons the plaintiffs requested the annulment of the rejection of review on abridged MA application dossiers by the defendant without presenting any legal reason except Article 36 of the Regulation on Marketing Authorisation of Medical Pharmaceutical Products on the grounds that it contravened Article 2 of the Law of Attorney.

In its defence, the defendant asserted that the disclosure of documents containing commercial and financial information and information relating to industrial applications constitutes a crime under the Turkish Penal Code No. 765 and would also lead to unfair competition.

The Council of State evaluated the parties' allegations within the framework of the TRIPS provisions, transparency of the administration and protection of competition. It considered

whether innovator companies monitoring the data submitted on the original medicine's MA dossier is effectively protected against unfair competition by the administration, if the innovator company has information about the presence of abridged MA applications made by referencing their dossiers.

The Council of State decided on the annulment of the mentioned implementation, emphasising that the provision placed in Article 36 of the Regulation on Marketing Authorisation of Medical Pharmaceutical Products concerning the confidentiality of the MA information is limited to the protection of the information in dossiers which has economic value. Rejection of information requests for obtaining information such as the existence and content of the abridged MA applications made by referencing the MA dossiers of the originator company is incompatible with the right of seeking legal remedies. In addition to this, the Council of State ruled that the information regarding whether abridged MA applications were available or not must be presented. If available, how many applications were made, who made these abridged MA applications and on which dates must be presented.

In line with the decision of the Council of State mentioned above, by applying to the TMMDA pursuant to the decisions of the Council of State and Attorneys' Law Article 2, information was requested with regard to whether new product applications and/or abridged MA applications or import MA applications were made or not. The MA dossiers of the product which is protected by the patent, data and other rights belonging to the innovator were shown. If such applications were made, information was provided about the number of these applications, the people who made these applications, related document registration including the dates, whether the applications made in this manner were still pending or not and whether they were withdrawn, rejected or returned for any reason or not, the stage of the pending applications and whether MA were granted or not.

Since 2007 when the decision of the MoH to not provide information was annulled, information requests of innovator companies have been responded to every year by the MoH and TMMDA, which was established afterwards.

In other words, pursuant to the decisions of the 10th Chamber of the Council of State, as from the decisions' dates, the defendant has to provide to the right owners information about whether abridged MA applications that show as a reference the MA dossiers owned by them are available or not, who made these abridged MA applications and on which dates, name, form and dosage information of the product subject of the application and whether the relevant MA was granted or not, as well as document registration information.

A change of approach

For the last seven to eight months, the administration completely changed its approach towards the information requests responded to by the TMMDA in accordance with the decision of the Council of State. The TMMDA started to refuse to provide information by stating that: "With regard to the mentioned pharmaceuticals, the "List of MAd Pharmaceuticals" available in the official internet site of the agency and the application numbers with respect to the products which comprise the same active ingredients and whose CTD Preliminary Examinations were completed, can be checked via the "Active Ingredients List". Your subsequent applications shall be considered accordingly."

The reason that the TMMDA's response is evaluated as a refusal is that the "Active Ingredients List" mentioned merely states in figures the number of applications that comprise the active ingredient, and the information concerning the product in these applications and the owners of these applications are not available in this list.

Additionally, the statement "your subsequent applications shall be considered accordingly" means that subsequent applications shall be rejected. As a matter of fact, this is the case and currently, all applications in this regard are rejected by the TMMDA.

In response to this situation, an innovator companies operating in Turkey applied to the administrative authority as stipulated in the Administrative Jurisdiction Procedures Law No. 2577 (AJPL a. 11) and asked the TMMDA to provide the information they had requested in their previous applications. However, the TMMDA did not respond to this application. Upon receiving this, the innovator company filed an annulment action requesting the annulment of this implementation by the TMMDA before the Administrative Court requesting the suspension of the execution.

If the execution of the implementation of the TMMDA is not suspended, then the innovator company will face irreparable damage. The generic company applying for abridged MA by referencing the original medicine protected by patent may supply its product by obtaining MA to the market as the generic product of the original product owned by the patent holder. Simultaneously with the supply of the relevant product to the market, the price of the original product will decrease at the rate of 60% pursuant to the Communiqué on the Pricing of the Medicinal Products for Human Use.

In the annulment of the administrative implementation with a request of suspension of execution action filed by the innovator company, the company has focused on a number of principles of administrative law in particular. These principles are the rule of law, transparency of the administration and the principle of equality. In this regard, the innovator company stated that without any legal reason or without any change in the current concrete situation, ceasing the existing implementation regarding information requests of innovator companies concerning abridged MA applications and preventing the right to access the information and documents possessed by the administration instead of providing clarity contradicts the following principles: the rule of law, transparency of the administration and the principle of equality and stability of the administration.

The proceedings filed by the innovator company are currently pending. Considering the effect of the result on the ability of all innovator companies operating in Turkey to effectively use and protect their patent rights, it is obvious that the decision will have a big impact. Beyond this specific result, direct application of the fundamental principles of administrative law to concrete disputes and discussion of these principles and consistency between decisions and previous decisions will have particular importance.

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