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Seeking Information on Pending MA Applications Is Lawful According to Administrative Court

As per article 9 of the Regulation on Licencing, which regulates "Abridged Application", if a pharmaceutical has been licenced before, it is not necessary to repeat the tests and research and the data of these tests doesn't have to be submitted for licencing again, only referencing to the licence information of the pharmaceutical that is pre-licenced is sufficient.

However, due to the obligation of the product which is subject to the reference application must be basically similar to the original product which is protected by patents, a strong risk of infringement emerges against the patent rights. Even though the licensing procedures are exempted from the patent right, in order to analyse whether the activities to be undertaken after granting license to the reference product would create a risk of patent infringement and to ensure that the patent rights emerge from the law are used effectively by the patent owners, the patent right holder should be informed on reference applications in question. Within this context, the attorneys of the pharmaceutical companies that owns the original product that is protected by patent, pursuant to Article 2 of the Attorneyship Act, request information from the Ministry of Health Turkish Medicines and Medical Devices Agency whether new product application and/or abridged authorization application or import permit application, referring to the authorization dossiers of their pharmaceuticals, under protection with patent rights or other rights, had been filled, if yes, the number of these applications and related applicants, document registry information, including dates thereof, whether such applications were pending or not, whether such applications were withdrawn,

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dismissed or returned for any purpose, the stage of pending applications, and whether an authorization was granted.

In fact, in 2007, the two cases that we brought before the State Council on behalf of our clients and on our behalf as a proxy, after the attorneys of the patent owner pharmaceutical companies requested this information and the Ministry of Health rejected these information requests, the Council of State decided to cancel the individual decision and actions of the Ministry of Health on refusing to provide information; and it held that the information of "whether an abridged licensee application has been made by referring to the license of the plaintiffs, and if so, the number of them and by whom" should be provided. This decision of State Council was regarded and the information request applications were duly answered with content by the Agency which is ministerial to Ministry of Health until June 2019

However, although there is no amendment in the circumstances or in the case law of the State Council, a second administrative lawsuit became inevitable due to the Agent's sudden renunciation from its lawful practice and leaving the right holders in the dark on the way to protect their rights by giving the response of "The requested information is included in the Licensed Pharmaceuticals List and Active Substance List published on the official website of TİTCK" to the information request applications of patent holder pharmaceutical companies.

As a matter of fact, in the Licenced Pharmaceuticals List or Active Ingredient List which the Agent has referred to; extremely important information such as whether the abridged license application has been made, who the applicant is, the application date and the status of the application are not included. These

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lists which do not include more than the number of the applications as in numbers, have led to a serious adjourn in the protection of the patent rights of the patent holder.

In this second lawsuit which is filed, the legal ground of the case was determined wrongfully and the case was dismissed by majority vote. However, in the dissenting opinion annotated in the decision, it is stated the documents and information requested are not trade secret, so rejecting the request for information instead of accepting it, is against the law.

As a result of the appeal brought against this decision, the District Court has dismissed the decision of the Court of First Instance and once again, similar to the previous decision of Council of State;

- As per article 39 of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") and article 28 of the Regulation on Licencing, the rule of confidentiality of information regarding applications made for obtaining a license for a product is limited to preventing the information and documents in the file from being viewed by others and protecting information that has economic value from being shared.
- It is possible to control whether the data submitted to the original pharmaceutical license file by the inventors are effectively protected against unfair competition by the administration, only by having information on the abridged license applications made with reference to the pharmaceutical licenses they have,
- Within this context, concluding that the applications made for receiving information by the manufacturer invention owners as trade secrets would mean restricting efficient use of right to legal remedies.

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The court held on cancellation of the response given by the Agency who is the defendant.

Evaluation

The unlawfulness of the Agency's non-response to requests for information was already determined by the State Council decisions years ago, and as a matter of fact, responding to the information request applications that is duly filed pursuant to the decision of State Council's has turned into a settled administrative practice. However, the fact that the Agent suddenly stopped providing the requested information in return to the applications for information contrary to the decision of State Council, its practices and law, has created an element of surprise among the sector. Receiving a decision in the same direction about this practice, the illegality of which was previously determined by the decisions of the State Council, strengthened the institution regarding the request for information of the original licence holder company on reference license applications. We are of the opinion that with this second decision, arbitrary changes in the attitude of the administration will come to an end and an administrative institution would be prevented from being an obstacle before the protection and regardfulness of the patent rights of the original licence holders.