

Patent Infringement – Unfair Competition

(*) Mecom Sağlık Ürünleri Sanayi ve Ticaret A.Ş. vs. Ministry Of Health

The court action (*) has been instituted with the request to cancel the decision of the Ministry of Health relating to the authorization and sale permission granted to Mecom Sağlık Ürünleri Sanayi ve Ticaret A.Ş. for the medicament named “Tarden 40 mg Film Covered Tablet” and the article 9 of the “Regulation for Regulatory Authorization of Medical Pharmaceutical Products” which constitutes the basis of this operation.

The plaintiff declares that he has conducted for many years research & development and clinic works, various tests and made big investments for the medicament named Lipitor containing Atorvastatin, that he has submitted with the Ministry file belonging to the product containing the chemical, pharmaceutical, biological information with clinical documents listed in article 8 of the Regulation and has obtained the authorization-sale permission and asserts that the article of the Regulation subject to the court action allowing the Ministry to grant authorization and sale permission to the equivalent (generic) medicament named “Tarden containing the same active substance and thereby the operation subject to the court action is contrary to the article 39 of the TRIPS agreement, to the Decree-Law no. 551 pertaining to the protection of patents, to the articles 56 and 57 of the Turkish Commercial Code and that these facts create an unfair competition against them while their intellectual rights are protected.

The article 8 of the Regulation provides the mandatory information and documents that have to be submitted during the application for the first authorization and sale permission of pharmaceutical product, whereas the article 9 provides the application of an other product equivalent to the product previously produced and present on the market. In such a case, the fact that when the Ministry by granting an authorization to a medicament for which it has been evidenced that it contains the same active substance for which the function and results are known does not refer to the conditions required in article 8, has been found to be lawful. In compliance with the interdiction in article 39 of the TRIPS agreement, article 36 of the Regulation provides that the Ministry is responsible for the protection of undisclosed information submitted to the Ministry by the applicant interested to obtain the authorization for the pharmaceutical product.

Under this circumstance, the assertion of the plaintiff that the undisclosed information belonging to the medicament which has obtained the first authorization is also used for the finalization of the equivalent

medicament has not been found to be lawful and the assertion that the Ministry does not protect this undisclosed information has been found to be unevicenced. According to the Regulation as it is not question to disclose the information submitted by the firm having obtained the first authorization from the Ministry to an other firm interested to obtain the equivalent medicament authorization, the assertion of the plaintiff that the subject article is contrary to the article 83 of the Decree-Law no. 551 and the provisions of the Turkish Commercial Code referring to the unfair competition have not been found to be lawful.

The Tenth Chamber of the Turkish State of Council has rejected the action for the above explained reasons (Decision no. 2002/3812-2004/4064-26 April 2004).