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District Court Ruling: Filing an Abridged Application within RDP Term is use of a Legal Right to file an Application and therefore does not constitute Unfair Competition

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Regulatory Data Protection (RDP) issues are dealt with only by the Licensing Regulation of the Ministry of Health (MOH) of Turkey. In principle the relevant provision grants protection of data of originators for a term of 6 years as of the date of first Marketing Authorisation granted in the EU. However there is no mechanism to prevent the Gx Company from using the data before expiry of the term. The MOH interprets the relevant article as a market exclusivity and allows abridged Marketing Authorisation (MA) applications filed by using the data of the originator within RDP term. The Gx companies mostly choose to take advantage of this interpretation in order to be ready to launch as soon as the RDP term is expired.

The only tool remaining in the hands of the owner of the regulatory data to protect its rights arising from the data is filing an unfair competition action against the Gx Company depending on the unfair competition provisions of the Commercial Code.

In one of these actions the defendant Gx Company filed an abridged application by using the data of originator and was granted an MA before expiry of the RDP term. The plaintiff data owner argued unfair competition on the grounds that the defendant used the data without satisfying any of the legal conditions for filing an abridged MA application and therefore unfairly benefited from the the data. The plaintiff argued that regulatory data is also connected to unfair competition law. Because, the subject of unfair competition law is to protect the labour, including efforts, know-how and investment, in accordance with the principle of labour against the commercial methods and applications, in accordance with the principle of integrity. The rights of establishments on data, which are the most valuable business products, are under protection in accordance with Article 54 and Articles 55/1(c), Article 55/1(d) and Article 55/1(e) of Turkish Commercial Code (TCC), along with the general provisions, protecting property right. The plaintiff further argued that the defendant party is the competitor of the plaintiff in economic life. Also it has filed a license application in order to seize a substantial share of the client's market, by producing and selling a product, which is identical to the pharmaceutical of the data owner. The unfair use of originator's data by the defendant party, without authorization, is an action, by itself, incompliant with the rules of integrity, given in Article 55 of TCC and constitutes unfair competition.

The Gx Company basically defended itself with the counter arguments that the MA application filed is a mere exercise of the legal right to apply and therefore the conditions of unfair competition have not been met in the concrete case. The Gx company mentioned as well that the common

wealth should be considered when the legal regulations are being interpreted and the interpretation of the plaintiff, which prohibits use of data within RDP term, extends the term for at least two years and as the price of the original pharmaceutical decreases up to 40% when a generic enters the market, such an extension of the RDP term will be a burden to the Government Budget.

The Court did not refer the case to a court appointed expert panel in order to determine if the data of originator has actually been used by the defendant or not. However in the reasoned decision the Court accepted and acknowledged the fact that the Gx Company use the data of the plaintiff –without permission- and before the RDP term is expired. On the other hand the Court ruled that filing an abridged MA application is to use the right to file an application under the Licensing Regulation of the MOH and use of a legal right cannot constitute unfair competition. While making this interpretation the Court chose not to evaluate the fact that the same Regulation also grants the regulatory data protection right to data owner and whether the right to file an abridged MA application and protection of the RDP rights conflict or not.

The data owner appealed the decision before the District Court emphasizing that there is no legal regulation which allows for the defendant’s subject matter action as the Regulation hereby forbids referring to the data of the pharmaceuticals for a certain period, which shows that the act of Gx Company is not pursuant to Regulation.

The District Court followed the reasoning of the first instance court and rejected the appeal of the data owner on the ground that filing an abridged MA application by referring to the dossier including the test results and clinical trial data is the mere exercise of the right to file an application depending on the legal regulation, thus the MA application cannot be evaluated as an act constituting unfair competition.

The data owner still has the right to appeal District Court decision before Courts of Appeal.

The main point to discuss is whether an abridged MA application can still be accepted as “legal” if it does not fulfil at least one of the legal conditions set in the Licensing Regulation. However the Regulation allows filing an abridged application by using a third party’s data only if:

- The product is basically similar to a prior licensed medical product in Turkey and the owner of the marketing authorization for the original medical product consented to use of the toxicology, pharmacology and/or clinical references available in the file of the original medical product,

OR

- The product subject to an established medical use with an acceptable level of efficiency and safety,

OR

- The product is basically similar to a medical product which is licensed and has an expired data exclusivity term.

It seems that it is now at the wisdom of the Courts of Appeal to lighten the Turkish practitioners if an abridged application can be sheltered under the roof of “using a legal right to file an application” if none of the “legal” conditions were satisfied in the application in question.

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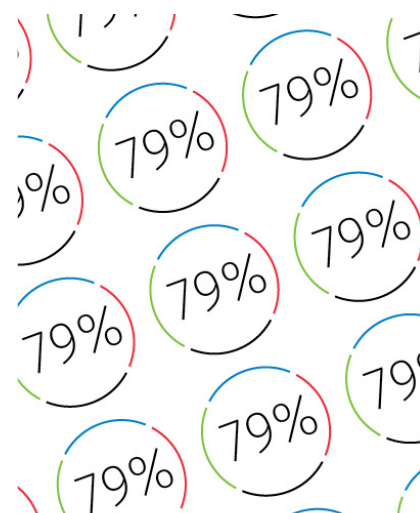
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