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Filing an abridged application within terms of RDP does not constitute unfair competition

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Regulatory data protection (RDP) terms are dealt with only in the Licensing Regulation of the Ministry of Health (MoH). In principle the provision grants the protection of data for six years following the first marketing authorisation for a drug granted in the European Union. However, there is no mechanism to prevent a generic drug company from using the data before the term expires. The MoH interprets the provisions as granting market exclusivity and allows abridged marketing authorisation applications filed by using the data of the originator within the RDP term. Generic companies generally choose to take advantage of this interpretation to be ready to launch as soon as an RDP term has expired.

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The only remaining tool available to enable data owners to protect their rights is by filing an unfair competition action against the generic company under the Commercial Code.

Facts

In one such action a defendant generic company filed an abridged application by using the data of the originator and was granted marketing authorisation before the expiry of the RDP term. The plaintiff data owner claimed that this constituted unfair competition on the grounds that the defendant used the data without satisfying any of the legal conditions for filing an abridged marketing authorisation application and therefore unfairly benefited from the commercial data. The plaintiff argued that regulatory data is also connected to unfair competition law and that the aim of unfair competition rules is to protect the labour – including effort, know-how and investment – in accordance with the principle of labour against commercial methods and applications that do not comply with the principle of integrity.

The rights of establishments on data, which are the most valuable business products, are protected under Articles 54, 55/1(c), 55/1(d) and 55/1(e) of the Commercial Code, along with the general provisions which protect property rights. The plaintiff further argued that the defendant party was a direct competitor and had filed a licence application to seize a substantial share of the client's market, by producing and selling a product that was identical to the plaintiff's products. The unauthorised use of the originator's data by

the defendant did not comply with the rules on integrity provided in Article 55 of the Commercial Code and therefore constituted unfair competition.

The generic company argued that it had a legal right to apply for the marketing authorisation application; therefore, the conditions of unfair competition were not met. The defendant also argued that common wealth should be considered when the legal regulations are interpreted and as the plaintiff intended to prohibit the use of data within the RDP term, this meant that the term was extended for at least two years. As the price of an original pharmaceutical product ordinarily decreases by up to 40% when a generic enters the market, such an extension of the RDP term would be a burden on the government budget.

Decision

The court failed to refer the case to a court-appointed expert panel in order to determine whether the data of the originator was actually used by the defendant. However, it acknowledged the fact that the generic company used the plaintiff's data – without permission – before the RDP term had expired. The court also ruled that filing an abridged marketing authorisation application is a legal right under the licensing regulation of the MoH; therefore, utilising a legal right does not constitute unfair competition. While making this interpretation the court failed to address the fact that the same regulation also grants RDP rights to the data owner or whether the right to file an abridged marketing authorisation application conflicts with the protection of RDP rights.

Appeal decision

The data owner appealed the decision before the district court and emphasised that no legal regulation exists which protects the defendant's action as all the relevant regulations prohibit referring to the data of a pharmaceutical product for a certain period, which demonstrates that the generic company's action were not legal.

The district court upheld the decision of the first-instance court and rejected the data owner's appeal. The court decided that the grounds for filing an abridged marketing authorisation application by referring to a dossier including test results and clinical trial data complies with the legal right to file an application; thus, the application did not constitute unfair competition.

The data owner still has the right to appeal the district court decision.

Comment

This case raises the question of whether a marketing authorisation application can still be accepted as being legal if it does not fulfil at least one of the legal conditions stipulated in the Licensing Regulation. However, the regulation allows for the filing of an abridged application by using third-party data only if:

- the product is basically similar to a prior licensed medical product in Turkey and the owner of the marketing authorisation for the original medical product consented to the use of the toxicology, pharmacology and clinical references available in the file of the original medical product;
- the product already has 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 is now the responsibility of the appeal courts to decide whether an abridged marketing authorisation application is protected under the legal right to file if none of the legal conditions were satisfied in the application.

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TAGS

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