



International report - District court confirms regulatory data protection is an IP right

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Regulatory data protection has been a contentious issue since it was introduced into Turkish law via the Ministry of Health Licensing Regulation. The most problematic areas are:

- the implementation of regulatory data protection as market exclusivity, despite contradictory wording in the Licensing Regulation; and
- limiting the regulatory data protection right to within the patent term.

When this issue comes before IP courts in cases of unfair use of data by third parties within the regulatory data protection term, most defendants contend that the commercial courts should have jurisdiction. However, in the case at hand, the IP Court itself rejected jurisdiction and the defendant appealed the decision before the district court.

Before dealing with the decision, the district court assessed data exclusivity protection under Turkish law. Subject to the data exclusivity right, the data was created by original pharmaceutical manufacturers and presented to healthcare authorities for marketing authorisation. The data was a result of the intellectual efforts of the owners; therefore, the right to such data is clearly an IP right.



**Selin Sinem
Erciyas**

Data exclusivity rights are regulated under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), which proposed the removal of commercial obstacles between member states and IP rights protection. Article 1, Paragraph 2 of TRIPs states that ‘intellectual property’ covers the rights provided in Sections 1 to 7 of Part II. Considering that protection of undisclosed information (Article 39, Section 7, Part II of TRIPs) governs data privilege rights, TRIPs therefore regards data exclusivity as an IP right. Further, the Industrial Property Law (6769) of Turkey essentially states that the jurisdiction of intellectual and industrial property rights courts includes all disputes related to industrial property rights. Similarly, the Turkish Commercial Code states that “the cases, related to Intellectual Property Law, should be heard by civil courts of intellectual and industrial rights with a single judge”. Accordingly, all disputes related to IP rights should be heard by intellectual and industrial property rights courts.

Considering this, the district court found that the case concerned data exclusivity rights and the protection of unrevealed data. Unrevealed data is within the scope of intellectual property pursuant to Articles 1 and 2 of TRIPs; such cases are always examined by civil IP courts and appealed before the 11th Chamber of the Courts of Appeal. Therefore, the civil IP courts do have jurisdiction to hear such unfair competition actions, depending on the breach of regulatory data protection rights.

As per Turkish law, the decision of the district court regarding lack of jurisdiction is final and binding, which cannot be appealed before courts of appeal. However, importantly, district court case law is not binding for local courts, making it possible for another IP court to reject the jurisdiction in the case of an action regarding regulatory data protection rights. Nevertheless, for consistency the district court can overrule a local court’s decision for the same reasons.

For further information please contact:

Selin Sinem Erciyas

Gün + Partners

www.gun.av.tr

Email: selin.yalincakli@gun.av.tr

Tel: +90 212 354 00 00