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The Turkish Competition Authority grants individual exemption to a second subcontracting agreement concluded with the same subcontractor in the same market taking into account localization of the import-dependent insulin industry and sustainability of the quality *(Novo Nordisk)*

ANTICOMPETITIVE PRACTICES, AGREEMENT (NOTION), BLOCK EXEMPTION (REGULATION), DISTRIBUTION AGREEMENT, PHARMACEUTICAL, MANUFACTURING, JUDICIAL REVIEW, TURKEY

Turkish Competition Authority, *Novo Nordisk*, Case 20-36/493-218, 28 July 2020 (Turkish)
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On November 5, 2019, Novo Nordisk Sağlık Ürünleri Ticaret Ltd. Şti. ("Novo Nordisk") applied to the Turkish Competition Authority ("Authority") for a negative clearance or an individual exemption with respect to a subcontracting agreement with Abdi İbrahim İlaç San. ve Tic. A.Ş. ("Abdi İbrahim"), a Turkish pharmaceutical company who had previously engaged in another subcontracting agreement with Sanofi Sağlık Ürünleri Ltd. Şti. ("Sanofi"). [*1*] The agreement with Sanofi, which had been previously granted individual exemption by the Competition Board ("Board"), [*2*] concerned the manufacturing of certain insulin products by Abdi İbrahim, whereas the new one with Novo Nordisk aimed at the formulation and filling of insulin cartridges, as well as the manufacturing and packaging of insulin injecting pens.

The Board did not grant a negative clearance to the agreement with Novo Nordisk since it contained restrictive provisions, such as the global non-compete obligation for the products with the same active pharmaceutical ingredient ("API"), the restriction on the use of the ingredients and the equipment allocated to the manufacturing of the products in question, and the non-disclosure provision with regard to information provided by Novo Nordisk. Furthermore, as Novo Nordisk's share in the relevant markets exceeded 25%, the Board concluded that the agreement would not fall within the scope of the Block Exemption Communiqué on Specialization Agreements No.2013/3, either.

In light of the above, the Board carried out a detailed individual exemption assessment on the agreement. As the agreement was aiming to localize the import-dependent insulin industry and develop the manufacturing and distribution of insulin products in Turkey, it was presumed that the agreement would improve both the production and distribution of the product, as well as promote economic and technical progress. The Board also expected this

collaboration to contribute to the sustainability of the quality in the formulation and filling activities of insulin cartridges, as these would be carried out in the Abdibio premises, a facility certified as employing Good Manufacturing Practices by the Turkish Ministry of Health. As it would allow the consumers to access low-cost products as a result of localization, the agreement was also expected to give a fair share of the resulting benefit to the consumers.

Within scope of the assessment, the Board considered that the above-mentioned restrictions were not stricter than required for the attainment of the objectives. The molecule-based non-compete obligations under the agreement would allow Abdi İbrahim to market, promote, distribute, and sell other insulin products in Turkey and all over the world. Thus, having filed for the marketing/distribution authorization for a similar product Basalog One, Abdi İbrahim would be able to distribute the product once the authorization is granted, despite an existing subcontracting agreement with Novo Nordisk. Further, the restrictions in the agreement did not affect the existing subcontracting agreement with Sanofi; even though such agreement also concerned the manufacturing of insulin products. The Board also found the non-disclosure obligation and the obligation to not use the equipment allocated for the Novo Nordisk products in other manufacturing activities, were commercially justified and proportionate to ensure the product safety.

On the other hand, in the assessment as to whether the agreement with Novo Nordisk would eliminate the competition in respect of a substantial part of the market, there were certain coordination and feasibility concerns, because of Abdi Ibrahim`s existing subcontracting agreement with Sanofi for competing products. In their responses to these concerns, the parties addressed the coordination risks as follows:

- The products in the two subcontracting agreements are based on different molecules and belong to different ATC-4 classes,
- Not only the main inputs but also the manufacturing processes of the two products are different in many aspects, so that neither company would be able to discover the other party's manufacturing costs.
- The sales prices of the medications in Turkey do not vary by manufacturing costs incurred by the manufacturers, due to the strict price regulations in force.
- Both agreements provide non-disclosure obligations to avoid any exchange of information.

The feasibility concerns are also addressed by the parties, as follows:

- The non-compete clause provided under the agreement with Novo Nordisk provides an API-based obligation.
- The agreement does not concern any products based on insulin Glarjim, insulin Glusilin or Lixisenatid APIs.
- The capacity of the Abdi İbrahim facilities is sufficient, in terms of both physical and the human resources, to fulfil both agreements concurrently and adequately.

Lastly, the parties also eliminated the concerns relating to the similar product Basalog One, which was expected to be imported in the Turkish market by Abdi İbrahim, since Abdi İbrahim would be able to market this product even if it was engaged under the subcontracting agreement with Novo Nordisk at the same time. All in all, the Board granted an individual exemption to the agreement; hence, both Novo Nordisk and Sanofi will be able to work with the same manufacturer for the competing products.

[1] The Board's Sanofi decision dated May 31, 2018, numbered 18-17/299-149

[2] The Board's Novo Nordisk decision dated July 28, 2020, numbered 20-36/493-218