Selective distribution systems in the pharmaceutical sector

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Introduction

Ankara's 13th Administrative Court ('Administrative Court') annulled[1] the Turkish Competition Board's ('Board') decision, dated 3 September 2020 and numbered 20-40/553-249, rejecting the exemption application of Johnson & Johnson Sıhhi Malzeme Sanayi ve Ticaret Ltd. Şti. ('J&J') ('Board's decision'). The distribution system that is assessed by the Board within the scope of J&J's exemption application concerns the distribution of four medicines, namely, Darzalex, Imbruvica, Stelara and Zytiga, manufactured by J&J by nine pharmaceutical warehouses within the scope of a quantitative selective distribution system ('Warehouse Sales Agreement' or the 'Agreement'). Through the exemption application, J&J requested the Board to determine that the Agreements benefit from the block exemption per the Block Exemption Communique No 2002/2 on Vertical Agreements ('Communique No 2002/2') or else, satisfies the conditions for an individual exemption as per Article 5 of the Law No 4054 on the Protection of the Competition ('Law No 4054').

The Board's decision

a. The vertical restrictions envisaged by the Agreement

The Agreement envisaged a quantitative selective distribution system by J&J covering the distribution of Darzalex, Imbruvica, Stelara and Zytiga within the pharmacy channel. The Board noted that the Agreement would reduce the number of warehouses in J&J's distribution network in the pharmacy channel from 40 to nine. The Board also remarked that per the selective distribution system these nine warehouses are prohibited to sell/supply the medicines subject to the Agreement with warehouses and/or distributors outside the scope of the selective distribution system and to barter such medicines with such warehouses and/or distributors. Additionally, the Agreement prohibited sales of the relevant medicines outside of Turkey or sales of such medicines within Turkey with the intent of resale to natural or legal persons located outside of Turkey. In that context, J&J was considered to have aimed to restrict parallel exports.

In terms of its assessment regarding the selective distribution, the Board emphasised that distribution systems that are non-qualitative (ie distribution systems where distributors are chosen based on objective criteria such as training of sales personnel, quality of service and product portfolio) and directly or indirectly restricting the number of re-sellers are within the scope of Article 4 of the Law No 4054. The Board further explained that quantitative and/or qualitative selective distribution systems could benefit from the block exemption per the Communique No 2002/2 even if it is applied simultaneously with vertical restrictions such as a non-compete clause or an exclusive distribution system, on the condition that (i) the market share of the supplier does not

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exceed 40% threshold and (ii) active sales between authorised distributors as well as active sales from authorised distributors to end-users are not restricted. That being said, the Board remarked that an assessment on whether a selective distribution system would benefit from block exemption or not would boil down to elements such as whether the nature of the product would require selective distribution, whether inter and intra brand competition is restricted and cumulative effects that may result from parallel networks.

b. The Board's assessment on the selective distribution system

Against the foregoing, the Board assessed whether the products in question require selective distribution by their nature and whether the criteria set forth for the selective distribution are necessary for effective distribution of such products. The Board further noted that selective distribution systems are generally applied for the products within automotive, cosmetic, or durable consumer goods sectors with a view to protect the brand image. Additionally, the Board noted that in such sectors the suppliers may be inclined to set criteria regarding the quality of sales points or sales personnel, professional and technical capabilities and after-sales repair and warranty services to protect the brand image.

In terms of its assessment on whether medicines would fall within the scope of products that would necessitate selective distribution by its nature, the Board remarked that wholesale level of medicine supply would not require such a distribution system by its nature. That being said, the Board dug deep into the medicines subject to the Agreement and assessed whether the respective products require a selective distribution system by their nature. To that end, the Board assessed whether following arguments of J&J would deem the relevant medicines eligible for a selective distribution system requirement: (i) Darzalex, Imbruvica, Stelara and Zytiga require expertise and are sold at a more expensive retail price than other medicines sold by J&J in the market, (ii) Darzalex and Stelara are biotechnological medicines that requires delivery under cold chain, (iii) Imbruvica and Zytiga are conventional products that are produced via high technology. Despite J&J's arguments, the Board concluded that the medicines at question do not differ from most of other medicines and did not necessitate a selective distribution system given that most of other medicines also require delivery under cold chain and are produced by way of a sophisticated technology. Furthermore, the Board remarked that the main purpose of the Agreement subject to the application is to implement an export ban and J&J aimed to monitor export of such products by way of limiting the number of its distributors. Relatedly, the Board considered such aim to be reasonable, however concluded that application of a selective distribution system is not necessary to achieve such purposes.

Consequently, the Board held that the distribution system at hand could not be deemed as a selective distribution system, due to the characteristics of the products. Hence, despite the fact that market shares of the products (ie Imbruvica, Zytiga, Stelara and Darzalex) subject to the Agreement were below 40% (ie, the threshold set forth under the Communique No 2002/2 was not exceeded for any of the pharmaceuticals concerned as of the date of the application[2]), the Board decided that the Agreement did not benefit from a block exemption, and J&J's preventing its authorised dealers from selling the relevant medicines to unauthorised resellers should be treated as a restriction on active and passive[3] sales. In light of this, the Board proceeded with an individual exemption analysis.

c. The Board's individual exemption analysis

Within the scope of the individual exemption analysis, the Board first remarked that the agreement at hand would not satisfy the criteria of ensuring new developments or improvements or economic or technical improvement in the production or distribution of goods, and in the provision of services, given that the

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distribution system at hand could not be deemed as a selective distribution system. In that case, the Board remarked, that the clause stipulating the selective distribution system of the Agreement would merely function as a restriction on resale activity of the distributors and it is not necessary for ensuring the availability of the relevant products within Turkey.

As regards to the criteria of customers benefitting from such developments and/or improvements, the Board first remarked that the Agreement may have positive effects for accessibility to the relevant products within Turkey given that the Agreement envisaged an emergency distribution system, which would enable allocation of additional quota of medicines to a given authorised distributor. That being said, the Board underscored that limiting the number of distributors that undertake the distribution of the respective products within Turkey would hamper and/or impede consumers' access to these medicines. To that end, the Board concluded that the consumers would not benefit from the developments and/or improvements arising from the Agreement.

In terms of the criteria of not eliminating competition in a significant part of the relevant market, the Board focused on J&J's market shares regarding these medicines within the pharmacy channel and the portion that these medicines take within J&J's total sales. Consequently, the Board concluded that the possibility that unauthorised pharmaceutical warehouses could not offer the medicines distributed under the Agreement under their own portfolio would have a negligible effect on the relevant market. To that end, the Board concluded that the Agreement would not eliminate competition in a significant part of the relevant market.

In terms of the criteria of not restricting competition more than necessary to achieve the goals set out in the first and the second criteria, the Board simply noted that the fundamental aim of the Agreement is to ban exports of the relevant products and the relevant clause of the Agreements setting out the selective distribution system would exceed beyond such aim and would restrict competition more than what is necessary to achieve efficiency in distribution and consumer benefit. To that end, the Board concluded that the Agreement failed to meet the final condition for being granted an individual exemption.

Against the foregoing, the Board concluded that the Agreement could not be granted individual exemption either.

Annulment decision of the Administrative Court

Following the Board's decision, J&J filed a lawsuit before the administrative courts for the annulment of the decision. In its examination, the Administrative Court noted that while quantitative selective distribution systems should be under a stricter scrutiny within the scope of Article 4 of Law No 4054, there is no legislative provision that prohibits quantitative selective distribution agreements.

Furthermore, the Administrative Court countered the Board's argument that the Agreement would hamper and impede the consumers' accessibility to the relevant medicines due to the selective distribution clause and limitation of the number of distributors, by way of indicating that all cities within Turkey would be supplied by at least two pharmaceutical warehouses within the scope of the distribution system set out by the Agreement. Furthermore, the Administrative Court noted that the emergency distribution system would also prevent supply bottlenecks. Additionally, the Administrative Court underscored that the Agreement did not restrict the pharmacy channel, which is the downstream market for the pharmaceutical warehouses that distribute the medicines and any pharmacy that would require the medicines at question could access to them.

In terms of the Board's approach that only the agreements covering the products that require selective distribution system by their nature would benefit the protective cloak of the block exemption, such as the products offered within automotive, cosmetic, or durable consumer goods sectors, the Administrative Court confined itself to address the Board's remarks within the scope of its individual exemption analysis and did not address the Board's remarks on how the block exemption rules would be

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applied to selective distribution systems. In that context, the Administrative Court considered the Board's argument that the pharmaceutical industry does not require technical and professional capabilities, after-sales services as unfounded, given that supply of pharmaceuticals requires technical and professional capabilities as well as after-sales feedback from the consumers within the scope of the applicable regulations to the relevant sector. That being said, the Administrative Court did not shed light on the issue on whether a product that does not require the selective distribution system by its very nature should be precluded from the protective cloak of the block exemption.

Lastly, the Administrative Court remarked that the Board's conclusion that the relevant clause of the Agreement stipulating the selective distribution system is not necessary to achieve the aim of export ban is unfounded, given that J&J substantiated that it could not prevent the exportation of such medicines despite the fact that these medicines are traced with barcode numbers labelled on them.

Accordingly, the court considered the fact that the Competition Authority can withdraw the exemption decision in case of a change in any event that constitutes the basis for the exemption decision within the scope of Article 13 of the Law No 4054, and therefore deemed the rejection of the exemption application is unlawful and annulled the Board's decision.

Main takeaways from the case

The Board's decision was a 'once in a blue moon' case in the sense that the Board refused to determine that the Agreement benefits from the protective cloak of the block exemption, despite the fact that J&J's market share for the medicines covered by the Agreement were each below 40% (ie, the threshold set forth under the Communique No. 2002/2 was not exceeded for any of the pharmaceuticals concerned as of the date of the application). The reason that such an approach was exceptional is that such a case is explicitly guided under the Guidelines on Vertical Agreements ('Guidelines'). Paragraph 172 of the Guidelines provides that both 'qualitative and quantitative selective distribution may benefit from the block exemption up to the 40% market share threshold, even if combined with other non-hardcore restraints, such as non-competition or exclusive distribution, provided active selling by the authorised distributors to each other and to end users is not restricted'. Additionally, the Guidelines explicitly sets out that 'The Communiqué grants exemption to selective distribution networks, regardless of the nature of the product'.

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Notes

1) **Ankara 13th Administrative Court's decision numbered 2021/778 E and 2022/966 K, dated 27 April 2022.**

2) **With the new amendment introduced by the Communiqué No 2021/4 on the Amendments to the Block Exemption Communiqué on Vertical Agreements ('Communiqué No 2021/4'), which promulgated in the Official Gazette dated 5 November 2021 and No 31650, the threshold regarding the supplier's market share(s) for the market(s) for the contract goods has now been lowered to 30%.**

3) **Fulfilling demands of customers from another buyer's region or customer group, which are not a result of active efforts by the buyer constitutes 'passive sales', even when the buyer delivers the goods to the customer's address. (Guidelines, para 24).**

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