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An In-Depth Analysis of the Turkish Competition Board's Biogen Decision on Exclusive Distribution Agreements in the Pharmaceutical Sector

Authors: Dr. Gönenç Gürkaynak, Esq.[1], Betül Baş, LLM, Petek Güven of ELIG Gürkaynak Attorneys-at-Law

This case summary includes an analysis of the Turkish Competition Board's ("***Board***") Biogen International GmbH ("***Biogen***") decision[2] in which the Board determined that the exclusive distribution agreement ("***Agreement***") between Biogen and Gen Ilaç ve Sağlık Ürünleri Sanayi ve Ticaret Anonim Şirketi ("***Gen Ilaç***") cannot be issued a negative clearance certificate pursuant to Article 8 of Law No. 4054 on the Protection of Competition ("***Law No. 4054***"), but may be granted individual exemption within the scope of Article 5 of the Law No. 4054.

I. Background Information

a. Parties and Scope

Biogen is a Biogen Group company active in the production, sale, import, export, and promotion of medicinal products for human use (such as biopharmaceuticals, pharmaceuticals, chemicals and other related products), as well as the management, acquisition and transfer of patents, trademarks, technical and industrial know-how.

Gen Ilaç's main activities include the production, purchase, sale, import, export and marketing of medicinal and health products. Gen Ilaç is engaged in the purchase and sale, import and export, production and marketing, contracting, representation and agency of chemical substances, diagnostic reagents, radioactive diagnostic kits, pharmacy and hospital supplies used in the medical and pharmaceutical industry, and medicines and preparations used in medicine and veterinary medicine for treatment and diagnosis.

The application concerned a request for a negative clearance certificate or an exemption to be granted to the Agreement signed between Biogen and Gen Ilaç in July 2014, which has been amended several times since its enforcement, with the most recent amendment in May 2022 ("***Final Amendment***") and extending the term of the Agreement until December 2024. While the Agreement initially aimed for Biogen to grant exclusivity to Gen Ilaç with respect to the distribution of Avonex, Tysabri, Fampyra, Tecfidera and Plegridy, which are medicinal products used in the treatment of multiple sclerosis ("***MS***"), in Turkiye and the Turkish Republic of Northern Cyprus ("***Northern Cyprus***") ("***Region***"), the Final Amendment introduced Spinraza, a drug used in the treatment of Spinal Muscular Atrophy ("***SMA***"), to the scope of the Agreement, upon Spinraza's licensing in Turkiye and receipt of all necessary approvals from the local regulatory authorities in Turkiye and Northern Cyprus. The Agreement provided that Gen Ilaç would be the license-holder for the marketing of the products covered

[1] Attorney at Law and Founding Partner of ELIG Gürkaynak Attorneys-at-Law, Istanbul, Türkiye. Honorary Professor of Practice at University College London (UCL), Faculty of Laws and Senior Fellow at University College London, Centre for Law, Economics and Society. Member of faculty at Bilkent University, Faculty of Law, Ankara, and Bilgi University, Faculty of Law, Istanbul

[2] The Board's *Biogen* decision dated 15.12.2022 and numbered 22-55/853-352.

by the Agreement (except for Spinraza, which would be subject to the exclusive distributorship after its license is approved in the Region) and would hold marketing licenses on behalf of Biogen.

The Agreement initially contained separate terms and commercial conditions for each product, none of which exceeded five years, and there was no provision for automatic renewal of the Agreement. In this context, the agreement did not contain a non-compete obligation for an indefinite period. However, the non-compete clause in the agreement was revised in the Final Amendment and Gen Ilaç and its subsidiaries were prohibited from directly or indirectly promoting, marketing, selling, manufacturing, importing, distributing or using in clinical trials, directly or indirectly, competing products within or outside the Region. This was due to the fact that these obligations were essensial for the protection of Biogen's know-how transferred to Gen Ilaç and that therefore it was essential that these obligations are valid throughout the term of the Agreement and that the provisions of the Agreement continue to apply for one year after the expiry and/or termination of the Agreement for any reason.

In terms of the relationship between the parties, the Agreement stated that Gen Ilaç was an independent contractor that purchases and resells products and provides services in its own name and on its own behalf, there is no proxy relationship between the parties, and the parties cannot create debts and obligations on behalf of each other. Furthermore, the Agreement allowed Gen Ilaç to enter into sales and/or promotional agreements with wholesalers and pharmaceutical warehouses in the Region at its own discretion and under its own responsibility.

b. Relevant Markets

When defining the relevant product market, the Board referred to the ATC classification by the European Pharmaceutical Marketing Association in parallel with the European Commission's approach. When the products subject to the Agreement are evaluated in terms of their ATC-4 classifications, Fampyra has the highest market share among the MS medicines, with Avonex, Plegridy, Tecfidera and Tysabri having very low market shares.

As for Spinraza, the medicine was granted a license in Turkiye in November 2022. The Board assessed that two other drugs used in the treatment of SMA, Evrysdi by Roche and Zolgensma by Novartis, were included in the Foreign Drug List in September 2020 and December 2020 respectively. While both Evrysdi and Zolgensma can be procured within the scope of the Legislation on Foreign Drug Supply and Use (with the Drug Supply Programme on behalf of the Patient) and therefore, there are a total of three products used to treat SMA, each of the drugs significantly differs from each other. Further, while Evrysdi has an ongoing marketing license application in Turkiye, unlike Spinraza, it is not included in the Social Security Institution ("***SSI***") Reimbursement List, and Zolgensma does not have a marketing authorisation license application and is not supplied in Turkiye. Moreover, the Board stated that although Spinraza has a high market share compared to its competitors due to being the first FDA-approved drug and having the lowest price, its market share decreased globally with the increased availability of Evrysdi and Zolgensma.

Accordingly, the Board held that although it is possible to define the relevant product market according to ATC-4 for Fampyra and active substance class for Spinraza, as a narrower relevant

product market definition will not have any effect on the result in terms of the issues in the case at hand, it is not necessary to make a precise market definition.

As for the relevant geographic market, since the production, sale, distribution, and marketing of Spinraza and Fampyra would be carried out within the borders of Turkiye, the Board defined the relevant geographic market "Turkiye" as a regional-level assessment was not necessary.

II. The Board's Assessments on Negative Clearance and Block Exemption

The Board first evaluated whether the Agreement would be eligible for a negative clearance certificate under Article 8 of Law No. 4054.

The Board found that the Agreement was a vertical agreement containing provisions restricting competition within the scope of Law No. 4054, such as exclusivity and non-compete obligations. Therefore, the Board held that the Agreement cannot be granted a negative determination certificate, and that it is necessary to evaluate whether the Agreement meets the exemption conditions regulated in Article 5 of Law No. 4054.

The Board assessed that while the respective market shares of Avonex, Plegridy, Tecfidera and Tysabri are each below the 30% threshold stated in Block Exemption Communiqué on Vertical Agreements ("***Communiqué No. 2002/2***") and the Agreement is not ineligible for block exemption in terms of these products, Spinraza and Fampyra would not be subject to block exemption in terms of their market shares, with Spinraza having a market share of 100% due to the fact that it is qualitatively different from other drugs used to treat SMA and does not have a complete substitute. Therefore, the Board held that the Agreement cannot benefit from block exemption and must be subjected to an individual exemption assessment instead.

III. The Board's Individual Exemption Test

Individual exemption is regulated by Article 5 of Law No. 4054, which states that four conditions must be satisfied for an agreement, decision or concerted practice to benefit from individual exemption. Accordingly, the Board evaluated the Agreement in terms of each of these four conditions, as follows.

i) New developments and improvements, or an economic or technical development in the production or distribution of goods and in the provision of services

Pursuant to the Agreement, provided that it is authorised in Turkiye, Spinraza will be available in the local market without the need to be procured from abroad through the Turkish Pharmacists' Association or Social Security Institution. Accordingly, the Board envisaged that if Spinraza is authorised by an undertaking established in Turkiye, the expenditures to be made for the importation of the drug will decrease, which may also relieve the burden on the Turkish social security system. Further, the Board stated that obtaining a marketing license for Spinraza in Turkiye, in addition to Spinraza being distributed by an undertaking resident in Turkiye may facilitate access to the medicine.

In addition, the Board assessed that the sales, promotion, and distribution of the pharmaceuticals would be carried out by Gen Ilaç to minimise operating costs and allocate resources effectively, which would allow Biogen to focus on innovative products. In this respect, considering the motivation of Gen Ilaç to realise the investments specific to the commercial relationship, the positive contribution to the sales, marketing and distribution activities of the pharmaceuticals and the cost savings which may result from the Agreement, the Board concluded that the Agreement meets the first condition of individual exemption.

ii) Consumer benefits

The current procurement process of Spinraza consists of imports from Germany through the creation of orders according to sales forecasts and shipments to hospitals after the completion of customs procedures. In contrast, the Agreement envisages cost savings to arise, supply periods to be shortened and consumers to benefit from a more favourable outcome in terms of prices, which are subject to intense regulations in Turkiye.

Thus, the Board assessed that the exclusivity provision in the Agreement is essential as it would enable Spinraza to be brought to the market faster and at a lower cost after it is licensed, which would result in consumers having easier access to medicine and consumer demand being met regularly. Therefore, the Board concluded that the Agreement meets the second condition of individual exemption.

iii) No elimination of competition in a significant part of the relevant market

As the Agreement regulates the sales, distribution, and marketing activities of Avonex, Tysabri, Tecfida, Fampyra, Plegridy and Spinraza exclusively by Gen Ilaç, the Board first assessed the competitive structure and the impact of the restriction of competition imposed by the Agreement on the level of competition in the relevant market.

The Board evaluated that there are many undertakings are active in the markets for MS medicines and that the markets are competitive with ongoing and prospective new entries. The Board further remarked that the market shares of the products covered by the Agreement, except for Fampyra and Spinraza, fall below the market share thresholds for block exemption, while with respect to Fampyra, it is observed that there are undertakings that are preparing to enter the market and will create competitive pressure despite Fampyra's high market share.

Additionally, the Board deemed it crucial to assess Gen Ilaç's relationship with pharmaceutical warehouses, stating that the existence of pharmaceutical warehouses with which Gen Ilaç has an exclusivity relationship may be considered as a vertical restriction that may cause competitive concerns. However, the Board concluded that the fact that the Agreement does not impose such an exclusivity relationship between Gen Ilaç and pharmaceutical warehouses and instead allows Gen Ilaç to establish a free commercial relationship with pharmaceutical warehouses, in addition to the positive contributions (such as investment incentives and increased pharmaceutical sales activities) which would arise out of the exclusivity relationship between Biogen and Gen Ilaç would contribute to the level of competition rather than eliminate it.

Therefore, taking into account factors such as the nature and scope of the co-operation arising from the Agreement, the position of the parties in the market, the existence of market power of the competitor undertakings that may exert competitive pressure on the parties in the relevant markets, the structure of the markets and the fact that the markets are subject to intense regulation, the Board concluded that the Agreement will not eliminate competition in a significant part of the market and meets the third condition of individual exemption.

iv) No restriction of competition more than required to achieve the goals in paragraphs (i) and (ii)

In relation to the last condition of individual exemption, the Board stated that the criterion of not restricting competition more than required should be made in relation to the exclusivity, the duration of the Agreement and the non-compete obligation that continues for one year after the expiry of the Agreement.

The Board first assessed that the exclusivity provision in the Agreement serves the purpose of fulfilling the obligations arising from the legislation and licensing procedure of Spinraza, as well as the necessity to foster the investments specific to the commercial relationship. The Board supported this view with reference to some of its precedents concerning the medical device sector[3] where it had held that the appointment of a sole authorised distributor in Turkiye by undertakings with a 100% market share does not give rise to competitive concerns due to the brand-based definition of the market. Moreover, the Board stated that the non-compete obligation in the Agreement is essential to protect the extensive and sensitive know-how shared within the scope of the commercial relationship between Biogen and Gen Ilaç. Therefore, the Board held that the so long as the non-compete obligation is limited to a reasonable period and scope to maintain the necessary investment incentive, the restrictive effect of the obligation on competition may not be significant.

Secondly, the Board assessed the duration of the non-compete obligation in the Agreement and remarked that the Agreement does not contain any provision allowing the automatic, tacit extension of the Agreement and that any extension of the term of the Agreement beyond December 2024 will be based on the free will of the parties. In light of this, as well as the relevant Turkish Competition Law regulations and past decisions of the Board[4], the Board held that the one-year period of the non-compete obligation following the expiry of the Agreement would not restrict competition more than required in terms of duration.

Finally, the Board reiterated that Gen Ilaç does not have an exclusive relationship with any pharmaceutical warehouse and is free to distribute its products to these warehouses and concluded that the Agreement is eligible for individual exemption under Article 5 of Law No. 4054 as it meets all four conditions.

[3] The Board's *Varian Medical Systems* (19.12.2019, 19-45/768-330) and *Radontek* (11.10.2018, 1838/617-298) decisions.
[4] The Board's *Bfit* decision (07.02.2019, 19-06/64-27).

IV. Conclusion and Analysis

The Board's *Biogen* decision serves as further guidance on the parameters taken into consideration by the Authority in the medical sector, which is under increasing scrutiny by the Authority following the inclusion of the biotechnology, pharmacology, and health technologies sectors within the scope of the local threshold exemption introduced by Communiqué No. 2022/2 on the Amendment of Communiqué No. 2010/4 on the Mergers and Acquisitions Requiring the Approval of the Competition Board, as well as the ongoing sector inquiry which began in 2021.

Article Contact: Dr. Gönenç Gürkaynak E-mail: gonenc.gurkaynak@elig.com

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