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Italian Competition Law Newsletter

Highlights

— The Council of State upholds the TAR Lazio judgment confirming an ICA Decision concerning Leadiant's abuse of dominant position in the Italian market for life-saving drugs used to treat a rare disease

— The Italian Competition Authority's notice on below-threshold concentration

— The Italian Competition Authority's revised merger guidelines and notification form

— The Regional Administrative Court of Lazio confirms the interim measures adopted by the ICA against Poste Italiane

The Council of State upholds the TAR Lazio judgment confirming an ICA Decision concerning Leadiant's abuse of dominant position in the Italian market for life-saving drugs used to treat a rare disease

In a ruling delivered on March 29, 2024,[1] the Council of State upheld the judgment of the Regional Administrative Court of Lazio (the "**TAR Lazio**"),[2] which, on July 20, 2023, dismissed the application for annulment lodged by Leadiant Biosciences Ltd., Leadiant GmbH and Essetfin S.p.A. (jointly "**Leadiant**") against the decision of the Italian Competition Authority (the "**ICA**") concerning Leadiant's abuse of dominant position (the "**Decision**").[3] In the Decision, the ICA imposed a fine of €3.5 million on Leadiant for charging excessive prices for a drug used for the treatment of a rare disease, i.e. cerebrotendinous xanthomatosis ("**CTX**"), which affects the human body's ability to metabolize cholesterols.

[1] Council of State, Judgment of March 29, 2024, No. 2967.

[2] TAR Lazio, Judgment of July 20, 2023, No. 12230, discussed in the July 2023 issue of this Newsletter: https://www.clearygottlieb.com/-/media/files/italian-comp-reports/italian-competition-law-newsletter-july-2023.pdf.

[3] ICA, Decision of May 17, 2022, No. 30156, A524 – *Leadiant Biosciences/Farmaco per la cura della Xantomatosi cerebrotendinea* (the Decision is discussed in the May 2022 issue of this Newsletter: https://www.clearygottlieb.com/-/media/files/italian-comp-reports/italian-competition-law-newsletter---may-2022.pdf).

Background

In 2008, Leadiant acquired the dossier and rights relating to Chenofalk®, a drug based on Chenodeoxycholic Acid ("**CDCA**"), from Dr. Falk Pharma GmbH, a German pharmaceutical company. This drug had initially been registered for the treatment of gallstones, but had later been used almost exclusively off-label for the treatment of CTX.

Leadiant changed the name of the drug from *Chenofalk®* to *Xenbilox®* ("**Xenbilox**"). Xenbilox was distributed in Germany, where Leadiant held the marketing authorization, and was exported from Germany to other Member States, namely the Netherlands, France and Belgium.

The acquisition made Leadiant the only credible active player at the European level in the commercialization of CDCA-based drugs. In 2008, Leadiant also entered into an exclusive supply agreement with Prodotti Chimici Alimentari S.p.A. ("**PCA**"), the only European supplier of Xenbilox's active ingredient (the "**Exclusive Supply Agreement**"). In 2014, Leadiant decided to apply for an orphan drug designation[4] and marketing authorization for its CDCA, specifically intended for the treatment of CTX ("**Leadiant CDCA**"). Leadiant CDCA is a hybrid drug of the reference drug Xenbilox, as the two products are chemically and pharmaceutically identical, but differ only for the therapeutic indication. Following the application concerning Leadiant CDCA, Leadiant started to significantly increase the price of Xenbilox (from €660 to €2,900 per pack).

In 2016, Leadiant also entered the Italian market. Until then, the supply of CDCA-based drugs in Italy had been guaranteed by hospital oncology pharmacies, which had been producing the product themselves in a galenic form in order to provide it to all patients suffering from CTX. In the same year, Leadiant renewed the Exclusive Supply Agreement with PCA for an initial duration of 7 years. The exclusivity allowed Leadiant to prevent Italian hospital oncology pharmacies from acquiring the active ingredient needed to produce the drug in a galenic form.[5] This caused CTX patients considerable inconvenience and forced hospitals to purchase Xenbilox, the only CDCA-based drug available on the market. As a result, Leadiant could extend its monopoly position into the Italian CDCA-based drug market.

Between 2016 and 2017, Leadiant withdrew Xenbilox from the market, and substituted it across Europe with Leadiant CDCA. In particular, in June 2017, Leadiant launched Leadiant CDCA in the Italian market. Shortly after, Leadiant started negotiating the price of Leadiant CDCA with the Italian Medicines Agency (the *Agenzia italiana del farmaco* or "**AIFA**"), and proposed a price of €15,000 per pack. AIFA did not consider this price to be justified, in light of: (i) the costs incurred by Leadiant (which did not provide details when so requested by AIFA); (ii) the activities carried out to obtain registration of the orphan drug; and (iii) the absence of any added therapeutic value of the drug. At the same time, Leadiant engaged in delaying tactics and obstructive behavior, such as failing to meet the deadlines set for the submission of economic proposals for the drug, despite AIFA's repeated reminders. As a result, the length of the negotiating procedure was extended by two and a half years. This worsened AIFA's negotiating position, which was already weak because of the need for the Italian National Health System (Sistema Sanitario Nazionale or SSN) to provide patients with an essential, irreplaceable and life-saving drug within a reasonable timeframe and at an economically sustainable price.

Eventually, Leadiant obtained a price for its orphan drug of over €6,200 per pack.

[4] Orphan drugs are medicines used for the diagnosis, prevention and treatment of rare diseases. Given their importance and the costs incurred to produce them, companies that hold a marketing authorization for an orphan drug enjoy 10 years of commercial exclusivity.

[5] In 2014, a consultancy firm advised Leadiant that the renewal of the exclusivity agreement with PCA was essential for the success of its pricing strategy in Italy, since this was the only way to stop the production of CDCA based drugs in a galenic form by hospital oncology pharmacies and to substitute it with Xenbilox.

The ICA Decision

The ICA found that Leadiant had implemented a complex abusive strategy by: (i) increasing the price of Xenbilox (its cheaper drug with the same active ingredient used off-label to treat CTX) even before obtaining the marketing authorization for Leadiant CDCA, as a means of preparing the market for the future sale of the orphan drug at higher prices; and (ii) artificially differentiating between Xenbilox and Leadiant CDCA, with a view to justifying the price difference between them. To this end, Leadiant assigned the ownership of Leadiant CDCA to a German company specifically set up for the only purpose of being the owner of the off-label drug (which was owned by a British subsidiary of the group), so that the owners of CDCA Leadiant and Xenbilox were apparently different.

In the ICA's view, Leadiant's abusive strategy allowed it to charge excessively high prices that bore no reasonable relationship to the economic value of Leadiant CDCA. In particular, the ICA concluded that the price agreed with AIFA at the end of the negotiation was: (i) disproportionate compared to the overall costs incurred by Leadiant; and (ii) not justified by the investment made in research and development, as well as the risk faced in the registration process.

The ICA found that the infringement was ongoing at the time of the adoption of the Decision, and therefore ordered Leadiant to take all necessary measures to set prices that were not unjustifiably high and to refrain in the future from engaging in similar conduct. In addition, the ICA imposed on Leadiant a fine exceeding the revenues from the sales of Leadiant CDCA in Italy in 2021.

The Judgment of the TAR Lazio

Leadiant submitted several pleas of appeal against the Decision, all of which were dismissed by the TAR Lazio.

First, the TAR Lazio rejected Leadiant's arguments that the ICA had violated the legal framework for the marketing of orphan drugs, and that Leadiant had not unduly emphasized the characteristics of the Leadiant CDCA, as this drug should not be considered a generic version of Xenbilox, but rather a new pharmaceutical product in terms of quality, efficacy and safety. The TAR Lazio agreed with the ICA's findings that Leadiant obtained a marketing authorization through an abbreviated procedure because of the chemical and pharmaceutical identity of the drug with its predecessor Xenbilox, and that the only real difference between the two drugs was the therapeutic indication. Therefore, the investment required to change the therapeutic indication did not justify the price increase charged by Leadiant.

Secondly, the TAR Lazio confirmed the ICA's findings that, since 2016, Leadiant has held a dominant position in the Italian market for the production and sale of CDCA-based drugs for the treatment of CTX due to significant entry barriers, such as: (i) the Exclusive Supply Agreement entered into with the only European supplier of Xenbilox's active ingredient; and (ii) the orphan drug marketing authorization obtained in 2017, which gave Leadiant a 10-year exclusivity on CDCA-based drugs, enforceable against both industrial and galenic manufacturers.

Thirdly, the TAR Lazio found that Leadiant deliberately prolonged the negotiation phase with AIFA because it was not able to justify the proposed price in the light of the costs incurred. This negotiation strategy aimed at maintaining the price initially charged for Leadiant's new product.

Finally, the TAR Lazio applied the *United Brands* test to verify whether the prices charged by Leadiant were abusive. The first part of the *United Brands* test asks whether there is an excessive difference between the costs actually incurred and the price actually charged. The TAR Lazio found that the ICA had correctly demonstrated the excessiveness requirement on the basis of two different methodologies: (i) the internal rate of return methodology, which takes into account the profitability of the product throughout its life cycle; and (ii) the cost-plus methodology, which compares the costs plus a reasonable profit margin with the price actually

charged. The TAR was satisfied with the two methodologies applied by the ICA, both of which showed that Leadiant CDCA sales generated excessive profits.

The TAR Lazio then turned to the second part of the *United Brands* test, aimed at verifying whether the prices were unfair. In this respect, the administrative court noted that the ICA correctly opted for the criterion of unfairness in itself, as it was impossible to assess the unfairness in comparison with competing products in the absence of substitutable drugs. The TAR Lazio concluded that the ICA rightly found the contested price to be unfair in itself, considering in particular the nature of the drug (whose active ingredient was already on the market), the limited investment undertaken in R&D activities, as well as the absence of added therapeutic value of the orphan drug compared to pre-existing therapies.

As a result, the TAR Lazio entirely dismissed the appeal brought by Leadiant and upheld the Decision.

The Judgment of the Council of State

On appeal, the Council of State fully confirmed the lower court's ruling.

First, Leadiant argued that the TAR Lazio limited itself to a formal review of the ICA's assessment, without carefully considering its various pleas. The Council of State rejected this objection, on the grounds that: (i) the TAR Lazio's reasoning was complete and correct overall; and (ii) in any event, the reasoning of the Decision was consistent with the factual background.

Secondly, the Council of State agreed with the TAR Lazio that, since 2016, Leadiant had held a dominant position in the Italian market for the production and sale of CDCA-based drugs for the treatment of CTX due to the presence of significant barriers to entry, including the Exclusive Supply Agreement. In addition, the Council of State shared the TAR Lazio's view that Leadiant had deliberately prolonged the negotiation phase with AIFA because it was not able to justify the proposed price based on the costs incurred, and wanted to maintain the price initially charged for Leadiant CDCA.

Thirdly, regarding the excessive price test, Leadiant argued, *inter alia*, that the application of the two-step *United Brands* test was flawed by numerous errors. However, the Council of State found that the ICA's analysis was in line with the case law of the CJEU and the Council of State itself, according to which the *United Brands* test requires verifying whether: (i) there is an excessive difference between the costs incurred and the price actually charged; and (ii) the price is unfair, either in absolute terms or in relation to competing products. According to the Council of State, the ICA correctly conducted this two-part test.

Fourthly, the Council of State also upheld the TAR Lazio's reasoning that the ICA had correctly taken into account the relevant legal framework for the marketing of orphan drugs, and that Leadiant had unduly emphasized the characteristics of the Leadiant CDCA in order to demonstrate that it could not be considered a generic version of Xenbilox, but a new pharmaceutical product in terms of quality, efficacy and safety. According to the Council of State, it is important not only to consider single, isolated initiatives (which may as such be compatible with sector-specific regulation), but also to examine the conduct as a whole, in order to verify whether it can give rise to an infringement of EU competition law.

Finally, the Council of State rejected the ground of appeal regarding the unlawful calculation of the amount of the fine. In particular, the Council of State upheld the ICA's finding that the infringement was extremely serious, given the importance of the right undermined by Leadiant's misconduct, namely the right to health of patients suffering from a rare and potentially deadly disease, for whom Leadiant CDCA treatment is essential.

The Italian Competition Authority's notice on below-threshold concentration

Background

On February 27, 2024, the ICA adopted a revised notice on the ICA's call-in powers on below-threshold concentrations (the "**Revised Notice**").[6] The Notice, which replaces the first version adopted on December 13, 2022 ("**2022 Notice**"), reflects the ICA's recently developed decision-making practice and aims to increase legal certainty.

1. Review of below-threshold concentrations

On August 5, 2022, the Italian Parliament adopted Law No. 118, the "*2021 Annual Competition Law*" (the "**2021 ACL**").

The 2021 ACL introduced Article 16, para. 1-bis, of Law No. 287/1990, which empowers the ICA to request the notification of below-threshold concentrations and review them when three cumulative conditions are met:

i. one of the two turnover thresholds provided for in Law No. 287/1990[7] is exceeded, or the combined aggregate worldwide turnover of the undertakings concerned exceeds €5 billion;

ii. the concentration raises competition concerns ("concrete risks to competition") in the national market, or in a substantial part of it, also taking into account possible detrimental effects on the development of small enterprises with innovative strategies;[8] and

iii. no more than six months have elapsed since the completion of the transaction.

The new power of the ICA aims at strengthening the merger control system, by preventing potentially problematic below-threshold transactions from escaping the ICA's scrutiny, particularly in the following areas:

i. digital economy and pharmaceutical sector, where so-called "*killer acquisitions*" may occur, *i.e.* transactions involving small or medium-sized newly-established companies with no or very limited revenues, which generally do not meet the EU and national turnover thresholds;

ii. traditional sectors where concentrations may have a significant impact on local markets, despite not meeting the turnover thresholds.

2. Review of below-threshold concentrations

The 2022 ACL raised a number of issues, in particular in relation to the assessment of the criterion of "concrete risks to competition" in the national market, or in a substantial part of it, which is rather vague and makes it complex for companies to self-assess whether the ICA could have an interest in reviewing the transaction.

The 2022 Notice failed in its attempt to provide clear and objective parameters on how to apply this criterion.

3. The Revised Notice

2.1 Assessment of the competitive risks

In line with the previous notice, the Revised Notice outlines the factors on the basis of which the ICA will assess the "*concrete risks to*

[6] To date, eight below-threshold notifications have been recorded: see ICA decisions of February 13, 2024, No. 31062, C12583 – *IGPDecaux/Clear Channel Italia*; February 27, 2024, No. 31097, C12608 – *Sage/Del Curto*; February 27, 2024, No. 31098, C12609 – *Sage/Morandi-Bortot*; February 27, 2024, No. 31099, C12610 – *Sage/Re Sergio Recycling*; March 26, 2024, No. 31137, C12615 – *Alpacem Cementi Italia/Ramo di azienda di Buzzi Unicem*; May 23, 2024, No. 31198, C12586 – *Ignazio Messina & C/Terminal San Giorgio*; May 28, 2024, No. 31222, C12607 – *Servizi Italia/Ramo di Azienda di Steris*; March 12, 2024, No. 31130, C12611 – *F2I Ligantia/SO.G.AER*.

[7] See fn. 5.

[8] Differently from the previous Notice of December 2022, the third condition no longer refers to "*prima facie evidence of the existence*" of concrete anticompetitive risks.

competition", notably the market structure, the total value of the transaction and the nature of the activities carried out by the undertakings concerned, with particular attention to the innovative potential of the business involved, which may not yet be reflected in the turnover.

In addition, the Revised Notice specifies that the ICA is unlikely to identify competition concerns in case of horizontal concentrations where:

i. the undertakings concerned hold a post-transaction combined market share below 25%; [9] or

ii. the post-transaction HHI is below 1000;[10] or

iii. the post- transaction HHI is between 1000 and 2000, with an increase in the HHI (so-called delta HHI) below 250; or

iv. the post-transaction HHI is above 2000, with a delta HHI below 150.

In the case of non-horizontal concentrations, the ICA is unlikely to request the notification of below-threshold concentrations where the undertakings concerned hold a post-transaction combined market share below 30% in each affected market, with a post-transaction HHI below 2000.[11]

2.2 Procedural amendments

From a procedural viewpoint, the Revised Notice amends the previous notice in relation to the extension of the time limit for notification.

2.2.1 Steps and time-limit

In the event that the ICA requests a notification pursuant to Article 16, para. 1-*bis*, of Law No. 287/1990, the parties must notify the concentration within 30 days. The notification must fulfil the same requirements as the ordinary procedure under Article 16, para. 1, of Law No. 287/1990. If the ICA considers that the proposed concentration is likely to raise anticompetitive risks in the national market, it shall open a Phase II investigation within 30 days of the notification. In any event, the request for notification pursuant to Article 16, para. 1-bis, of Law No. 287/1990 does not preclude a request for referral to the Commission pursuant to Article 22 of Regulation (EU) No. 139/2004.

According to the 2022 Notice, the 30-day time limit for the notifying party to notify the transaction could have been extended by up to 30 days in the case of "*exceptional circumstances*". The Revised Notice allows the ICA to grant an extension of even more than 30 days, irrespective of the existence of "*exceptional circumstances*", upon reasoned request of the undertakings concerned.

2.2.3. Voluntary notification

The 2022 Notice allowed the parties to submit a voluntary notification of below-threshold concentrations, in case the concentration was "*likely to create concrete risks to competition*". In this respect, the Revised Notice adopts a lower standard. The parties can now submit a voluntary notification in any case in which the concentration could "*have an effect on competition*".

The Revised Notice also introduces a time limit for voluntary notifications. The deadline is two months after the closing of the transaction. Following the submission of the voluntary notification, the ICA has 60 days to request a formal notification.

[9] The Notice explicitly recalls the European Commission's Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings (OJ C 31, 5.2.2004).

[10] The Herfindahl-Hirschman Index ("HHI") is calculated by summing the squares of the individual market shares of all the firms in the market.

[11] The Notice explicitly recalls the Commission's Guidelines on the assessment of non-horizontal mergers under the Council Regulation on the control of concentrations between undertakings (OJ C 265, 18.10.2008).

The Italian Competition Authority's revised merger guidelines and notification form

Overview

On February 27, 2024, the ICA adopted Communication No. 31089,[12] setting out its revised guidelines on how to notify a concentration to the ICA pursuant to Article 16 of Law No. 287/1990 (the "**Communication**"), and a new version of the merger notification form (the "**New Form**"),[13] both of which apply from May 1, 2024.

The revision of the guidelines and notification was due to two main reasons.[14] First, it takes into account the recent changes in the merger control system introduced by Annual Competition Law No. 118/2022 (the "**2021 ACL**") and Annual Competition Law No. 214/2023 (the "**2022 ACL**"),[15] as well as the developments in the ICA's decision-making practice.[16] Secondly, it aligns national merger control rules with the principles established at the EU level, in particular in the European Commission's Jurisdictional Notice.[17]

The key changes are set out below.

1. Only one version of the New Form

The New Form reflects at the national level the revised version of the Form CO for merger notifications to the European Commission.[18]

The New Form is now available in only one version, irrespective of the parties' market shares, thus eliminating the previous distinction between extended and simplified forms. In practice, notifying parties have a limited additional burden to collect and provide further information in relation to the so-called "*affected*" markets. The newly introduced Section VI.2 of the New Form on non-affected markets requires minimal data and even less where there are no horizontal overlaps or vertical relationships, a brief description being sufficient.

This New Form can also be used to notify below threshold concentrations to the ICA as well as all full function joint ventures.

2. The definition of "*affected*" markets

One of the main changes introduced by the New Form concerns the definition of "*affected*" markets.

First, the market share thresholds to categorize a market as an affected market are increased and aligned with those set at the EU level.[19] In particular, a market is considered to be an affected market when one of the following conditions is met:

a. the parties' post-transaction combined market share is equal to or above 20%, when the increase in the Herfindahl-Hirschman Index

[12] It replaces the previous version, i.e., the ICA's communication of July 1, 1996 as amended on September 6, 2017.

[13] ICA, Communication of February 27, 2024, No. 31089, available at https://www.agcm.it/dotcmsdoc/formulario/p31089_Comunicazione_operazioni_concentrazione.pdf.

[14] See Communication, p. 3.

[15] The 2022 ACL extends the deadline for the in-depth phase II proceedings in merger control cases from 45 to 90 days.

[16] The reform introduced by the 2021 ACL is illustrated in the Cleary Alert Memorandum of August 2022, available at https://www.clearygottlieb.com/-/media/files/alert-memos-2022/italian-competition-law-reform.pdf. First, as mentioned above, the 2021 ACL introduced the possibility for the ICA to request the notification of below threshold mergers and to review the transaction. Secondly, the 2021 ACL replaced the substantive "*dominance test*" applied in the past by the ICA, focusing on the "*creation or strengthening of a dominant position in the national market*", with the so-called "*significant impediment of effective competition test*", similar to the test provided for by Article 2(2) and (3) of the EU Merger Regulation. Thirdly, all full-function joint ventures are now subject to merger control rules, regardless of their "*concentrative*" or "*cooperative*" nature.

[17] Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No. 139/2004 on the control of concentrations between undertakings (the "**EU Merger Regulation**"), OJ 2008/C 95/01.

[18] This was part of the so-called 2023 Merger Simplification Package, which is illustrated in the Cleary Antitrust Watch "*The European Commission Simplifies Its Merger Control Review Process*", by Antoine Winckler, Robbert Snelders & Timothy Noelanders on April 27, 2023, available at https://www.clearyantitrustwatch.com/2023/04/the-european-commission-simplifies-its-merger-control-review-process/.

[19] In particular, the market share thresholds to categorize a market as an affected market are now aligned (albeit minimal differences) with the definition of "affected markets" set out at paragraph 25 lett. g) of the Form CO.

(delta HHI) is above 150, or above 50% in other cases (whereas according to the previous notification form the threshold was 15%); or

b. one of the parties holds a market share equal to or above 20% and another party is a potential competitor or has entered the market in the last five years; or

c. one of the parties will hold a post-transaction market share equal to or above 30% and at least one other party operates in a downstream or upstream market (both the upstream and the downstream markets are to be deemed affected); or

d. one of the parties holds a market share equal to or above 30% and another party owns goods or assets (such as raw materials, infrastructure, data, or intellectual property rights) which are significant to that market or a contiguous and closely related market; or

e. one of the parties operates in a market which is contiguous and closely related to a product market where another party is active and the individual or combined market share held by the parties in either of the two markets is equal or above 30%;

Secondly, the New Form identifies some additional affected markets, which take into account the fact that, following the 2021 ACL, the ICA can request the notification of below-threshold concentrations and review them, when they can have detrimental effects on the development of small enterprises with innovative strategies. In particular, according to the New Form, an affected market exists when the target company in an acquisition or a merging party is:

— an important innovator or conducts potentially important research activities; or

— a start-up or a new operator with a high innovative potential that may not yet be reflected in the turnover.[20]

3. Concentrative joint ventures

The New Form contains a new section dedicated to cooperative effects of joint ventures,[21] which takes into account the recent amendment introduced by the 2021 ACL, according to which any types of full-function joint ventures – *i.e.*, not only concentrative (as per the previous merger control regime) but also cooperative ones – are now subject to the ICA's merger control scrutiny, in line with the EU merger control system.[22]

4. Additional information and documents

Finally, the New Form requires the notifying parties to provide a set of supplementary information and documents regarding affected markets (in line with the EU Form CO),[23] efficiency claims,[24] internal documents,[25] potential competitors and innovation,[26] and the possible strengthening of buying power

[20] See Section VI.1 of the New Form.

[21] *Id.*, Section IX.

[22] See Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No. 139/2004 on the control of concentrations between undertakings, OJ 2008/C 95/01, para. 92.

[23] See Section VI.1 of the New Form.

[24] *Id.*, Section VIII.

[25] *Id.*, Section X.

[26] *Id.*, Section VI.

The Regional Administrative Court of Lazio confirms the interim measures adopted by the ICA against Poste Italiane

On March 26, 2024, the Italian Competition Authority (the "**ICA**") adopted interim measures against Poste Italiane S.p.A. ("**Poste Italiane**") in the context of the investigation into Poste Italiane's alleged refusal to grant competitors access to its infrastructure. By an order issued on April 26, 2024, the Regional Administrative Court of Lazio (the "**TAR Lazio**") upheld the ICA decision.

Background

Poste Italiane's conduct

Poste Italiane is the provider of the universal postal service in Italy. As it is entrusted to carry out a service of general economic interest (a "**SGEI**"), Poste Italiane is subject to specific obligations. In particular, pursuant to Article 8, para. 2-*quater*, of Law No. 287/90 ("**Article 8***(2-quater)*"),[27] if Poste Italiane makes available to its affiliates or subsidiaries goods or services which it has access to in its capacity as a SGEI provider, it must make such goods or services available also to competitors, on equivalent terms.

Since the beginning of 2023, PostePay S.p.A. (a subsidiary of Poste Italiane, "**PostePay**") has been promoting and selling electricity and natural gas supply at the retail level under the brand Poste Energia. In carrying out this activity, PostePay has been exploiting, under a license from Poste Italiane, the entire network of post offices to which the latter has exclusive access in its capacity as a SGEI provider.

The opening of the proceedings

When certain competitors of PostePay in the market for the retail supply of electricity and natural gas asked Poste Italiane to grant them access to its infrastructure on the same conditions as PostePay, Poste Italiane refused. As a result, the Italian trade association of companies operating in the electricity and gas sectors filed a complaint to the ICA, asking for the adoption of interim measures with a view to:

— preventing Poste Italiane from allowing PostePay to promote and market in its offices Poste Energia's supply offers; and

— obliging Poste Italiane to grant third parties access to the premises made available to PostePay, on the same conditions.

On January 30, 2024, the ICA opened an investigation into Poste Italiane's conduct and at the same time initiated interim proceedings. In the ICA's view, Poste Italiane may have infringed Article 8(2-*quater*) by granting exclusively to PostePay an advantage that is almost impossible for competitors to replicate.

The Interim Measures

In its decision of March 26, 2024, the ICA imposed interim measures against Poste Italiane (the "**Decision**").

Contrary to Poste Italiane's view, the ICA found that its power to grant interim relief is not limited to proceedings relating to restrictive agreements and abuse of dominance, but also applies in relation to proceedings brought under Article 8 of

[27] Which reads: *"In order to ensure equal opportunities for economic initiative, where an [undertaking that has been entrusted by legal provision to manage a SGEI or operates as a monopoly] makes available any goods or services, including information services, which are available exclusively to it as a result of its management of a SGEI or of its activities as a monopoly, to a subsidiary or an affiliate in a market distinct [from that in which it itself operates], such an undertaking shall make such goods or services available, on equivalent terms, to other undertakings operating in direct competition with its subsidiary or affiliate".*

Law No. 287/90. Since the ICA is empowered to adopt interim measures in any case where the risk of serious and irreparable damage to competition exists, the ICA considered that it has the same power also in relation to Article 8 proceedings, which is also aimed at preserving the overall competitive structure of the market.[28]

Prima facie case

Poste Italiane claimed that it was exempt from the application of Article 8(2-*quater*) on the ground that is covered by the so-called "**Polis Exemption**" under Article 1, para. 6, of Decree Law No. 59/2021.

However, the ICA interpreted the Polis Exemption in the sense that it only exempts Poste Italiane from the application of the provision in relation to the realization of a specific project for making changes in certain post offices in municipalities with less than 15,000 inhabitants in order to allow public administration services to be offered in remote areas (the "**Polis Project**"). The ICA held that a wider application of the Polis Exemption would give rise to an unjustified distortion of competition to the benefit of Poste Italiane. The ICA referred in this respect to Article 106(2), TFEU, under which derogations from Competition Law provisions are only allowed in exceptional cases and to the extent they are necessary and proportionate to pursue an objective of general interest.

As a result, the ICA considered that the Polis Exemption does not apply in relation to post offices located in municipalities with more than 15,000 inhabitants, or in any event not included in the scope of the Polis Project, and concluded that it was likely that Poste Italiane had infringed Article 8(2-*quarter*).

Urgency

According to the ICA's investigation, Poste Energia's offers for the retail supply of electricity and natural gas were remarkably successful as they attracted more than 500,000 new subscribers in about ten months. Most of these subscriptions were made at post offices.

The ICA considered that this success was likely due to PostePay being granted the possibility to reach the large customer base of post offices. Moreover, the fact that many customers usually pay their energy bills at post offices gives PostePay an opportunity to propose its supply offers to customers of competing suppliers.

The ICA pointed out that the exclusive competitive advantage enjoyed by PostePay was even more relevant considering that, by July 1, 2024, more than four million energy consumers will be obliged to switch from the protected regime to the free market, and to choose between their previous supplier or a new one.

As a result, the ICA considered that Poste Italiane should have allowed access to its premises also to PostePay's competitors as a matter of urgency, in order to allow such operators to propose their energy supply offers to new potential customers before July 1, 2024.

The interim measures imposed

The ICA imposed several interim measures on Poste Italiane. In particular, it ordered Poste Italiane to:

— allow PostePay's competitors' access to all post offices not included in the scope of the Polis Project, on the same conditions offered to PostePay;

[28] Pursuant to Italian law, in order to impose interim measures, the ICA is required to establish: (i) the existence – *prima facie* – of an infringement of Article 8 of Law No. 287/90 by Poste Italiane (prima facie case); and (ii) the urgency to intervene due to the fact that the alleged infringement is likely to cause serious and irreparable damage to the competitive dynamics in the markets concerned (urgency).

— publish on its website a fair and non-discriminatory access procedure and a price list, and admit requesting operators to adequate physical spaces in which to set up promotional stands and carry out marketing activities for their supply offers; and

— respond to any access requests within 15 days from their receipt, granting access on a 'first come, first served' basis.

The TAR Lazio's Ruling

Poste Italiane applied to the TAR Lazio for annulment of the Decision.

On April 26, 2024, the TAR Lazio rejected Poste Italiane's application.

In particular, the TAR Lazio confirmed the ICA's interpretation in relation to the limited scope of the Polis Exemption. The Court also confirmed that the ICA is empowered to impose interim measures in relation to proceedings brought under Article 8 of Law No. 287/90.

Finally, the TAR Lazio considered that the interim measures imposed were not such as to irreparably harm Poste Italiane's interests. It concluded that, in balancing the opposing interests at stake, the need to ensure that a level playing field between competitors is maintained must prevail over Poste Italiane's commercial interests.

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