March 2021

Italian Competition Law Newsletter

Highlights

— The ICA ends its investigation into an alleged abuse of dominance by gas distributor Italgas Reti by accepting and making its commitments binding

— The Council of State turns to the ECJ again in the *Roche-Novartis* case

The ICA accepts commitments by Italgas Reti for an alleged abuse of dominance in the gas distribution sector

On February 23, 2021, the Italian Competition Authority (the "**ICA**") made legally binding the commitments offered by Italgas Reti S.p.A. ("**Italgas**"), a company active in the gas distribution sector in the province of Venice, which belongs to the Italgas group (the "**Decision**").[1] Italgas' commitments were found to address adequately the ICA's concerns that the company may have abused its dominant position in the local market for the provision of natural gas distribution services, in violation of Article 102 TFEU. According to the ICA's decision to open the investigation, Italgas' conduct was allegedly aimed at delaying the launch in 2018 of an open tender procedure for the provision of gas distribution services in a number of municipalities in the province of Venice (the "**Tender**").

The relevant legal framework

Article 14 of Legislative Decree No. 164/2000 (the "**Letta Decree**") characterizes natural gas distribution as a public service, to be provided under an exclusive concession granted by each municipality for its own territory. According to Article 15(1) of the Letta Decree, the gas distribution service is entrusted by local authorities exclusively through competitive tender procedures, for a period not exceeding 12 years, without prejudice to the obligation of the outgoing operator to continue the management of the service until the effective date of the new assignment.

Pursuant to Decree Law No. 159/2007 laying down urgent economic measures for social development and equity, converted with amendments into Law No. 222/2007, the existing municipal concessions

[1] ICA Decision No. 28585, Case A540 – *Condotte abusive Italgas/Atem Venezia 1*.

were consolidated into area concessions ("*concessioni di ambito*") and 177 such areas were identified (so-called "**ATEMs**"). According to Article 24(4) of Legislative Decree No. 93/2011, implementing Directives 2009/72/CE and 2009/73/CE concerning common rules for the internal market in electricity and gas, respectively, ATEMs are the geographic areas for the award, through competitive tender procedures, of natural gas distribution concessions.

The legal framework currently in force imposes disclosure obligations on outgoing operators in favor of contracting authorities. In particular, two categories of information are deemed to be necessary for a tender to be launched, and must be provided:

— information on the structure and the ownership of the gas distribution network, pursuant to Articles 4 and 5 of Ministerial Decree No. 226/2011, laying down the criteria for the entrustment of the gas distribution service (as amended in 2015), including, in particular, the inventory of the network[2] and additional information necessary for the preparation of the call for tender;[3] and

— information relating to the enhancement of the gas distribution network,[4] according to paragraph 19 of the Ministry of Economic Development's Guidelines of May 22, 2014 (the "**MISE Guidelines**").

The Tender and the opening of the investigation

The Tender involves an ATEM comprising eight municipalities in the province of Venice ("**ATEM Venezia 1**"). Italgas is entrusted with the provision of gas distribution services in most of the municipalities included in ATEM Venezia 1, namely Venezia, Chioggia, Jesolo, Cavallino Treporti, Caorle and Eraclea. In the municipalities of Venezia and Chioggia, 2I Reti gas has a marginal position. Another competitor, Infrastrutture Distribuzione gas S.p.A. is entrusted with the provision of gas distribution services in the municipalities of Cavarzese and Cona. According to the Italian Regulatory Authority for Energy, Networks and Environment, Italgas controls roughly 97% of the natural gas distribution market in the province of Venice.

Italgas operated under a legal monopoly for more than 40 years by virtue of a concession agreement with the City of Venice, which expired in 2012. Following an open tender procedure in which ATEM Venezia 1 participated in 2015, which the City of Venice later cancelled, the two parties were embroiled in a long-running administrative dispute over the ownership of certain distribution networks in ATEM Venezia 1.

The ICA started its investigation into Italgas' alleged abusive conduct on the basis of a complaint filed by the City of Venice. According to the said complaint, Italgas stalled efforts to establish competitive bidding procedures for gas distribution by refusing to supply the necessary data and information to prepare tender documents, as required by Articles 4 and 5 of Decree No. 226/2011 and paragraph 19 of the MISE Guidelines.

Definition of the relevant market and Italgas Reti's dominant position

The sector affected by the alleged abuse of dominance relates to the gas distribution service, which is provided under a legal monopoly. Its boundaries reflect the geographic scope of each exclusive concession, which currently have a municipal dimension. In the vast majority of local

[2] Pursuant to Article 1(1) of Decree No. 226/2011, such inventory consists of the maps and the description of the networks and plants relating to the natural gas distribution service. The maps consist of the representation, at least graphic, of the plants and networks, which includes information on the material of the pipes, their diameter and the operating pressure. Such information must be provided in an open format and interoperable, as clarified by Article 2 of the MISE Decree of May 11, 2016.

[3] This includes a status report on the distribution network, as well as data and information on communication protocols concerning equipment measurements, and the financial obligations relating to investments made in the previous period of assignment and on public and private contracts relating to the performance of the distribution service and to plant ownership.

[4] In particular, summaries of: (i) the main characteristics of the plant; (ii) the methodology used for the enhancement of the plant; and (iii) the economic data for the evaluation of the reimbursement value as well as the economic data relating to tariff regulation, and various economic indicators. Such information must be updated at least on December 31 of the second year preceding the one in which the call for tender is published.

markets, the gas distribution service is provided under an extension regime, since, on the one hand, the initial concessions expired and, on the other hand, calls for tenders involving the ATEMs have not been launched yet.

Currently, Italgas has a legal monopoly in four of the eight municipalities of the Venice province (Jesolo, Cavallino Treporti, Caorle and Eraclea) and is the main operator in the municipalities of Chioggia and Venice.

The allegedly abusive conduct

According to the Decision, Italgas allegedly abused its market power by refusing or delaying the submission to the City of Venice as the contracting authority of certain data and information essential to prepare the Tender documents and to launch future gas tenders to increase competition in the market.

The ICA asserted that such information was available exclusively to the company. Therefore, its refusal or delay in supplying it to the City of Venice likely amounted to an abuse aimed at slowing down the Tender.

The ICA also took the view that the conduct in question could affect the opportunities for other qualified national and EU competitors to participate in future tenders for the assignment of the gas distribution service in ATEM Venezia 1, so as negatively to affect the conditions of provision of the service to end users.

The commitments

In order to address the ICA's concerns, Italgas offered the following commitments (the "**Commitments**"):

— To hand over to the City of Venice all essential data and financial information – updated as at December 31, 2017 and December 31, 2018 – necessary to launch the Tender (the "**First Commitment**"). The ICA took the view that, as a result of this commitment, the competition concerns relating to the delay in preparing the documents necessary to launch the Tender would be overcome, also considering that Italgas committed proactively to assist the City of Venice significantly to speed up the process for the publication of the call for tender;

— To provide the City of Venice with detailed maps of its distribution network in shapefile format, including data on communication protocols, equipment measurements, public and private contracts related to plant ownership and status reports on the current distribution networks (the "**Second Commitment**"). The ICA noted that the Second Commitment is complementary to the First one, to the extent that it allows the City of Venice to proceed more quickly with the preparation of the Tender documents, and at the same time facilitates competitors' access to such documents and strengthens their ability to present competitive offers;

— To provide the City of Venice with data and information as per the First Commitment, updated as at December 31, 2019 (the "**Third Commitment**"). According to the ICA, although outgoing service providers' compliance with disclosure obligations is required by law, pursuant to Article 4(3) of Decree No. 226/2011, the Third Commitment allows a significant reduction of the time required for publication of the call for tender, considering that Italgas committed to provide the essential data and information on a purely voluntary basis, in the absence of any previous request from the City of Venice;

— With respect to all future ATEM tenders, to hand over to all contracting authorities detailed plans concerning the process of providing essential data and information. Italgas also agreed to appoint a contact to assist the contracting authority in processing (and understanding) the data supplied, and to provide the ICA with a half-yearly report concerning the above mentioned planning (the "**Fourth Commitment**"). The ICA took the view that the Fourth Commitment will result in the setting-up of a new procedure

making it possible for Italgas to engage in formal dialogue with contracting authorities of the ATEMs in which it is the outgoing operator. In particular, systematic planning of information flows from Italgas Reti to the contracting authorities (through the definition of a binding time schedule) could make the relevant tender procedures easier and quicker to set up, ensuring the development of effective competition; and

— With respect to all future ATEM tenders in Italy, as opposed to those to be organized by the contracting authorities of the Venice province only, to submit to contracting authorities also a methodological note clarifying the criteria followed by Italgas in the performance of its disclosure obligations (the "**Fifth Commitment**"). The ICA noted that this commitment will contribute to the speeding up of the process for collecting all essential data and information. Moreover, considering that it will be implemented by the most important operator at the national level, it will would be capable of reducing any possible competitive concerns in other ATEMs.

The said commitments were offered until completion of all tenders for the assignment of the natural gas distribution service in Italy.

In light of the above, the ICA concluded that the Commitments – as clarified by Italgas in light of the results of the market test – are suitable for remedying the competition concerns that led the ICA to open the investigation. Indeed, the implementation of the Commitments will facilitate the launch of the Tender and allow competitors to participate on a more equal footing, because no single operator will hold all of the essential information for the entire municipality's gas distribution network. The ICA also took the view that the commitments would improve competition in future tenders.

The ICA also noted that certain Commitments were implemented by Italgas even before the ICA closed its investigation.

The Council of State turns to the ECJ again in the *Roche-Novartis* case

On March 15, 2021, the Council of State delivered a non-final judgment (the "**New Judgment**") dismissing in part, on procedural grounds, the applications brought by F. Hoffmann-La Roche Ltd. and Roche S.p.A. ("**Roche**"), as well as Novartis Farma S.p.A. and Novartis AG ("**Novartis**"; jointly, the "**Parties**"), for the revocation of a 2019 judgment of the same court (the "**2019 Judgment**").[5] By the 2019 Judgment, the Council of State upheld the ruling of the Lazio Regional Administrative Court (the "**TAR Lazio**") as well as the 2014 ICA decision fining the Parties for their participation in an alleged cartel (as described below; the "**ICA Decision**").[6]

Moreover, by separate order issued on March 18, 2021 (the "**Order**"), the Council of State stayed the revocation proceedings pending before it and referred the matter to the Court of Justice of the EU (the "**ECJ**") for a preliminary interpretative ruling.

[5] Council of State Judgments, respectively, No. 2222/2021 and No. 4990/2019 (the latter upholding TAR Lazio Judgment No. 12168/2014). Pursuant to Article 106 of the Code of Administrative Procedure, a judgment delivered by the Council of State can be challenged before the same Chamber of that court, adjudicating in a different composition, on the ground of error of fact. According to the settled case law on the admissibility of such applications, an error of fact giving rise to revocation must: *(i)* result from the court's erroneous or omitted perception of the material content of the documents filed in the proceedings, which has led the court to take a decision on the basis of a false factual assumption, i.e. by considering proven a fact which is actually non-existent, or non-existent a fact which has actually been proven; *(ii)* not relate to a contentious point on which the decision has expressly ruled; and *(iii)* concern a decisive element in the ruling to be revoked. An error of fact exists also where the court has failed to rule on one or more pleas, or has ruled on issues or objections that the parties did not raise in their pleadings in the case, due to an oversight in the court's process of perception of the records of the proceedings.

[6] ICA decision of February 27, 2014, No. 24823, Case I760, *Roche-Novartis/Farmaci Avastin e Lucentis*.

Background

The ICA Decision

In 2014 the ICA fined the Parties for an anticompetitive agreement aimed at creating an artificial product differentiation between two drugs, which were allegedly equivalent for the treatment of age-related macular degeneration ("**AMD**") (Lucentis and Avastin *off-label*), in order to influence prescriptions by doctors and health services and thereby increase the sales of the more expensive drug.[7]

According to the ICA, the Parties' anticompetitive strategy aimed at reducing the use of Avastin in ophthalmology and increasing the use of Lucentis, thus significantly raising the costs borne by the Italian health service. This objective was pursued *inter alia* through the dissemination of allegedly misleading information aimed at casting doubts over the safety of the use of Avastin for AMD, despite the lack of scientific evidence supporting such doubts. The ICA established that the Parties' conduct amounted to a market-sharing agreement constituting a by-object restriction in violation of Article 101 TFEU, and fined the Parties approximately €180 million overall. Both the TAR Lazio and the Council of State on appeal upheld the ICA Decision.

The 2019 Judgment

In particular, on July 15, 2019, the Council of State fully rejected the Parties' appeals against the TAR Lazio's ruling. The 2019 Judgment heavily relied on the guidance provided by the ECJ in an interpretative ruling it delivered in January 2018 (in Case C-179/16), following a preliminary reference by the Council of State, in the appeal proceedings concerning the ICA Decision, in December 2015 (the "**Preliminary Ruling**").[8]

The following aspects of the 2019 Judgment – concerning the relevant market definition and the dissemination of allegedly misleading information – are noteworthy, as the Parties subsequently based their applications for revocation on the following issues:

(i) The relevant market definition

As mentioned above, the ICA included the two drugs in the same relevant market. According to the Parties, the ICA had wrongly defined the relevant market on the ground that the regulatory framework did not provide for substitutability between off-label medicines and medicines that are authorized for a specific use. The 2019 Judgment rejected this argument. In the Council of State's view, insofar as sector regulation did not prohibit the off-label use of Avastin, nor its repackaging for such off-label use, the ICA was right in defining the relevant product market as comprising both Lucentis and Avastin used *off label*.

(ii) The dissemination of allegedly misleading information

The Council of State dismissed the Parties' claim that the ICA was wrong to find that they had colluded in order "*to manipulate the public's risk*

[7] In the late 1990ies, U.S. pharmaceutical company Genentech developed a revolutionary active ingredient called bevacizumab (later sold under the brand name Avastin) to treat certain types of cancer. Bevacizumab was licensed to its parent company Roche for distribution outside of the U.S., and was granted a market authorization by the European Commission in 2005. In parallel, having found that Avastin could also help treat MAD, Genentech developed and started selling ranibizumab, a specific molecule (sold under the name of Lucentis) that it considered more appropriate for treating AMD for a number of technical reasons. Lucentis was licensed to Novartis for distribution outside of the U.S., and was granted an EU market authorization in 2007. As Avastin was about 30 times cheaper that Lucentis, some doctors administered Avastin "off-label" for AMD treatment, on their own responsibility, where, on the basis of an assessment of individual patients, they concluded that it was necessary to do so to meet a patient's specific needs. Roche, however, never applied for an authorization to market Avastin for AMD treatment. In light of the objective differences between the two molecules, a scientific debate arose in many countries on the respective safety and efficacy of Avastin and Lucentis for AMD treatment.

[8] The ECJ established the following principles in the Preliminary Ruling: (i) both a medicinal product authorized for the treatment of a specific disease and a medicinal product used off-label for the treatment of the same disease, may be considered as forming part of the same relevant market, where there exists a relationship of substitutability between the authorized and unauthorized drugs. In order to establish whether such a relationship exists, the competition authority must take account of the outcome of the examination (if any) by the competent authorities or courts (relating to the conformity of the product at issue with the applicable provisions governing the manufacture or the marketing of that product) by assessing any effects it may have on the structure of supply and demand; (ii) an arrangement put in place between the parties to a licensing agreement for the exploitation of a medicinal product, which, in order to reduce competitive pressure on the use of that product for the treatment of given diseases, is designed to restrict the conduct of third parties promoting the use of another medicine for the treatment of those diseases, does not fall outside the application of Article 101 TFEU on the ground that the arrangement is ancillary to the license agreement; and (iii) an agreement between companies marketing two competing drugs, which is intended to provide misleading information on the negative side effects of the use of one of them for the off-label treatment of a disease, with a view to reducing the competitive pressure resulting from such use on the other medicine, constitutes a restriction of competition by object falling outside of the legal exception of Article 101(3) TFEU. It is for national courts to assess whether such concerted campaign is indeed objectively misleading.

perception" of the off-label use of Lucentis, as well as to "*artificially*" differentiate between two medicinal products which, in the ICA's view, were in fact equivalent (and, as such, substitutable) from the point of view of safety and effectiveness in the treatment of AMD.

The Parties later applied to the Council of State for revocation of the 2019 Judgment on grounds of error of fact. In particular, according to Roche, the Council of State committed errors of fact with regard to: (a) the definition of the relevant market, particularly by failing to establish the unlawfulness of the conditions under which Avastin was repackaged and prescribed with a view to its off-label use (the "**First Plea**"); and (b) the allegations of the lesser safety of off-license Avastin compared to Lucentis, which were characterized as being misleading in nature (the "**Second Plea**"). Novartis challenged the 2019 Judgment on grounds of error of fact with respect to point (b) above only, and in connection with Novartis AG's alleged liability.

More specifically, Roche claimed that the Council of State: (a) did not investigate the possible unlawfulness of demand (prescription) and supply (repackaging) of Avastin as an off-label product, and upheld the ICA Decision, notwithstanding the fact that several regulatory authorities and courts had reached the conclusion of their illegality; and (b) upheld the ICA Decision, which established the existence of a by-object restriction, without even investigating whether the information disseminated was in fact misleading, which was, however, a distinct element required in order to find a restriction by object, in light of the preliminary ruling of the ECJ. Novartis's claims refer to point (b) above only, and to the fact that the Council of State overlooked that Novartis AG could not be held directly or indirectly liable for the alleged cartel.

The Parties also argued that, even in the absence of an error of fact – and, therefore, if the Council of State declared inadmissible one or both of the first two pleas –, the Court should nonetheless find that its 2019 Judgment unlawfully departed from the preliminary ruling of the ECJ because it failed to carry out the factual verifications that the ECJ had expressly required it to do, with respect to points (a) and (b) above.

In this respect, Roche also asked the Council of State to rule on whether the Italian legal system is incompatible with EU law – particularly with the duty of sincere cooperation between the Union and the Member States' authorities, pursuant to Article 4(3) of the Treaty on European Union – because it does not allow for the revocation of a ruling of a national court on the basis that it violates EU law, in particular the principles of EU law affirmed by the ECJ in a preliminary ruling delivered in main proceedings pending before the same referring court.

The New Judgment

By the New Judgment, the Council of State declared the parties' applications partly inadmissible on procedural grounds. The First Plea and the Second Plea were declared inadmissible as the Council of State found that the 2019 Judgment had already adjudicated those issues.

The Council of State held that the Parties extensively put forward their arguments concerning the alleged cartel in the appeal proceedings for the annulment of the TAR Lazio judgment. Therefore, by having abusive recourse to the revocation remedy, they merely reiterated their defenses to call into question the Court's assessment.

According to the Council of State, what the Parties claimed to be an erroneous perception by the court of the material content of the documents submitted in the proceedings constituted instead, at the most, an error of assessment or of interpretation of the facts, concerning an issue that the judgment fully covered, which as such could not be challenged by an application for revocation. Moreover, the Council of State emphasized that, according to settled case law, the fact that a court does not expressly rule on every single argument put forward by a party in support of its claim does not constitute a ground for revocation.

For the same reasons, the Council of State also rejected Novartis's pleas concerning Novartis AG's liability.

With respect to the ground of revocation concerning the violation of EU law, the Council of State decided to ask the ECJ to deliver a second preliminary ruling (see below). It is noteworthy that, under Italian law, since the revocation proceedings are still pending, the 2019 Judgment has not yet acquired the force of *res judicata*.

The Order

On March 18, 2021, the Council of State, by means of the Order, referred to the ECJ three preliminary questions,[9] seeking guidance on: (i) whether the 2019 Judgment violated an earlier preliminary ruling delivered by the ECJ in the same case, also calling into question the allocation of competence between the ECJ and national courts; and (ii) the lawfulness of the Italian rules of procedure, insofar as they do not provide for a case of revocation in the event of a violation of EU law by the Court that delivered the judgment being challenged, even when the lack of such remedy results in a final Court ruling contrary to EU law.[10]

[9] Namely: Question 1
May the national court, against whose decisions there is no judicial remedy under national law – in proceedings in which the party's plea is directly aimed at claiming infringement of the principles laid down by the ECJ in the same proceedings in order to have the contested judgment set aside – verify whether the principles laid down by the ECJ in the same proceedings have been correctly applied in the specific case, or is it for the ECJ to make that assessment?

Question 2
Has the 2019 Judgment violated, in the sense envisaged by the parties, the principles expressed by the ECJ in its preliminary ruling in relation to: (a) the inclusion in the same relevant market of the two medicinal products without taking into account the positions adopted by the competent authorities that would have ascertained the unlawfulness of the demand and supply of Avastin off-label; (b) the failure to verify the alleged misleading nature of the information disseminated by the companies?

Question 3
Do Articles 4(3), 19(1) TEU and 2(1) and (2) and 267 TFEU, also interpreted in light of Article 47 of the Charter of Fundamental Rights of the European Union, preclude a framework such as the one laid out by Articles 106 of the Italian Code of Administrative Procedure and 395 and 396 of the Italian Code of Civil Procedure to the extent it does not permit the use of a remedy directed at challenging the judgments of the Council of State that are in breach of the judgments of the ECJ, and in particular of the principles of law affirmed by the ECJ in a preliminary ruling?

[10] Council of State, Order No. 2327/2021. The case number of the new preliminary reference procedure before the ECJ is C-261/21.

AUTHORS

Valerio Cosimo Romano
+39 06 6952 2267
vromano@cgsh.com

Alessandro Comino
+39 02 7260 8264
acomino@cgsh.com

Natalia Latronico
+39 02 7260 8666
nlatronico@cgsh.com

Chiara Militello
+39 06 6952 2613
cmilitello@cgsh.com

Riccardo Tremolada
+39 02 7260 8222
rtremolada@cgsh.com

Riccardo Molè
+39 02 7260 8684
rmole@cgsh.com

Ilaria Tucci
+39 06 6952 2674
itucci@cgsh.com

Francesco Trombetta
+39 02 7260 8636
ftrombetta@cgsh.com

Elio Maciariello
+39 06 6952 2228
emaciariello@cgsh.com

EDITORS

Giulio Cesare Rizza
+39 06 6952 2237
crizza@cgsh.com

Gianluca Faella
+39 06 6952 2690
gfaella@cgsh.com

SENIOR COUNSEL, PARTNERS, COUNSEL AND SENIOR ATTORNEYS, ITALY

Mario Siragusa
msiragusa@cgsh.com

Matteo Beretta
mberetta@cgsh.com

Marco D'Ostuni
mdostuni@cgsh.com

Giulio Cesare Rizza
crizza@cgsh.com

Gianluca Faella
gfaella@cgsh.com

Fausto Caronna
fcaronna@cgsh.com

Saverio Valentino
svalentino@cgsh.com

Luciana Bellia
lbellia@cgsh.com

Marco Zotta
mzotta@cgsh.com

© 2021 Cleary Gottlieb Steen & Hamilton LLP
Under the rules of certain jurisdictions, this may constitute Attorney Advertising.

21.0427.01_042821