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Italian Competition Law Newsletter

Highlights

— The ICA imposes fines of over €287 million on the members of two separate alleged cartels in the markets for corrugated cardboard sheets and cases

— The Council of State upholds the TAR Lazio ruling confirming the 2014 decision by which the ICA fined Novartis and Roche for an anticompetitive agreement aimed at creating an artificial product differentiation between two drugs that were allegedly equivalent for the treatment of age-related macular degeneration and other serious vascular eyesight conditions, in order to influence prescriptions by doctors and health services and thereby increase the sales of the more expensive drug

The ICA imposed fines of €287 million on the main manufacturers of corrugated cardboard sheets and cases for two separate cartels

On July 17, 2019, the Italian Competition Authority (the "ICA") imposed fines in excess of €287 million on 23 companies for two distinct anticompetitive agreements in breach of Article 101 TFEU (the "Decision" and the "Infringements", respectively).[1] According to the ICA, the two cartels were implemented in two different markets which were vertically related to each other, namely the upstream market for corrugated cardboard sheets (the "Sheets Cartel") and the downstream market for corrugated cardboard cases (the "Cases Cartel"). The Infringements allegedly also involved the relevant trade association *Gruppo Italiano Fabbricanti Cartone Ondulato* ("GIFCO").

Background: four leniency applications

The ICA's investigation was initiated on the basis of the complaint filed in October 2016 by a trade association of non-vertically integrated box manufacturers (*Associazione di categoria degli scatolifici non verticalmente integrati*, "ACIS"), concerning an anticompetitive agreement on the prices of and sale conditions for corrugated cardboard sheets, to the detriment of the companies that used this product as an input to manufacture cases for final consumers.

[1] ICA decision No. 27849, Case I805, *Prezzi del cartone ondulato*.

Furthermore, four companies submitted leniency applications, acknowledging their participation in the Infringements. While the first applicant applied for leniency shortly after ACIS's complaint, the other applicants did so between July and August 2018, *i.e.*, more than a year after the commencement of the procedure.

Two distinct infringements

In the Decision, the ICA concluded that the parties' conduct amounted to two separate single, complex and continuous infringements, *i.e.*, the Sheets Cartel and the Cases Cartel, which took place from 2004 and from 2005 until 2017, respectively.

The ICA found that 20 companies (*i.e.*, the main national operators active in the production and marketing of corrugated cardboard sheets, accounting for approximately 90% of the domestic market), as well as GIFCO, took part in the Sheets Cartel. The Sheets Cartel was aimed at: (i) fixing the price for the sale of corrugated cardboard sheets to non-integrated manufacturers of corrugated cardboard cases; and (ii) fixing and coordinating the volume of production, as well as production plant downtime and shut-downs, in order to reduce the output so as to support the increase in the price of the sheets and preserve profitability.

Regarding the Cases Cartel, the ICA took the view that it involved 24 companies (*i.e.*, the main national operators active in the production and marketing of corrugated cardboard cases), as well as GIFCO, and was aimed at: (i) fixing the level of general increases in the prices of corrugated cardboard cases to all customers; (ii) partitioning clients (so-called "non-aggression pact") and supply contracts (so-called "non-belligerency pact"); and (iii) defining other relevant contractual terms, such as payment terms.

According to the ICA, both cartels had a two-tier structure: (i) summit meetings organized on a nationwide basis, attended by a limited number of undertakings, where general indications on what ought to be done were agreed; and (ii) regional meetings organized on a narrower territorial basis, which followed and implemented at a local level the indications of the summit meetings. The parties' top management attended the summit meetings, whereas the regional meetings were attended by local managers or plant directors of the parties. The Cases Cartel also included: (i) more specific triangular meetings and interactions between competitors, in which specific shared customers (and their tenders) were discussed; and (ii) sector-specific meetings, dedicated to discussions on cases for specific industries (such as ceramics, and fruits and vegetables). GIFCO allegedly played a primary role in monitoring the cartels, as it distributed monthly and half-yearly production data among the participants. According to the ICA, the Sheets Cartel was implemented in a more frequent and regular manner than the Cases Cartel.

The ICA found that the Infringements were "*clearly distinguished from the product, subjective, structural and temporal points of view, as well as by the aim that each of them pursued*".[2] Moreover, the Infringements: (i) were allegedly implemented in two different (albeit vertically related) product markets; (ii) mostly involved different parties, given that only nine companies took part in both the Sheets and the Cases Cartel; and (iii) diverged also from the point of view of their respective content and functioning.

Calculation of the fines

In view of the duration and gravity of the Infringements, the ICA imposed on the members of the two cartels an overall fine of more than €287 million. In particular: (i) a total fine of approximately €110 million was imposed on the companies that participated in the Sheets Cartel; and (ii) a total fine of approximately €178 million was imposed on the members of the Cases Cartel.

Some of the companies were found to have played a particularly active role in the Infringements. Accordingly, the ICA applied a 15% aggravating circumstance in the calculation of their fines.

[2] *Id.*, § 373.

Interestingly, one of these companies was the first leniency applicant in connection with the Sheets Cartel. Moreover, a 15% aggravating circumstance was applied in the calculation of the fines imposed on other companies that refused to cooperate with the ICA's investigation.

The ICA also applied mitigating circumstances to reward the implementation of effective compliance programs and the marginal role played by some companies in the Infringements. In addition, in light of the specific circumstances of the case, the ICA granted additional discounts by departing from the general methodology for the setting of fines, as set out in its Fining Guidelines (the "Guidelines").[3] In particular, the ICA granted: (i) a 20% reduction to the companies which (also in light of their smaller size) played a minor role in the Infringements; and (ii) a 15% reduction in the fine for the Sheets Cartel imposed on those companies which, being vertically integrated and active in both markets, were also involved and fined for their participation in the Cases Cartel.

The 2014 ICA decision that fined Novartis and Roche for an anticompetitive agreement aimed at creating an artificial differentiation between two allegedly equivalent medicinal products for the treatment of age-related macular degeneration, is upheld by a final ruling of the Council of State

On July 15, 2019, the Council of State rejected an appeal filed 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") against a judgment issued in 2014 by the Regional Administrative Tribunal for Latium (the "TAR Lazio").[4] As a consequence, the 2014 decision by which the ICA fined the Parties approximately €180 million overall for a violation of Article 101 TFEU (the "Decision")[5] became final. According to the Decision, the Parties colluded with a view to creating an artificial differentiation between two medicinal products that were equivalent for the treatment of eye diseases, in order to increase sales of the more expensive one.

Factual background

Avastin and Lucentis are drugs developed by Genentech, a company belonging to the Roche group. Genentech licensed the commercial exploitation of Avastin and Lucentis to Novartis and Roche, respectively.

In 2005, the Italian Medicines Agency ("AIFA") authorized the marketing of Avastin for the treatment of tumors. Shortly thereafter, in 2007, AIFA authorized Lucentis for the treatment of eye diseases. In the timeframe in which Lucentis was waiting to be put on the market, some physicians noticed that Avastin could also be used off-license for the treatment of age-related macular degeneration and other eye diseases, although it was authorized only in oncology. Since Avastin was less expensive than Lucentis, it started to be widely used as an off-label medicine for the treatment of eye diseases, although Genentech and Roche (as market authorization holders) never sought Avastin's registration for ophthalmologic use.

The Decision declared the Parties liable for putting in place an anticompetitive strategy aimed at artificially differentiating between the

[3] Guidelines on the method of setting pecuniary administrative fines pursuant to Article 15, paragraph 1, of Law No. 287/90, §34.

[4] Council of State, judgment No. 4990/2019 (the "Judgment").

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

two drugs, with a view to 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 *inter alia* pursued, in the ICA's view, through the dissemination of information designed to create doubts over the safety of the use of Avastin for the treatment of eye diseases, despite the lack of scientific evidence supporting such doubts. Accordingly, the ICA found that the Parties' conduct amounted to a market-sharing agreement constituting a by-object restriction of Article 101 TFEU, and imposed on each of the Parties a fine of approximately €90 million.

The Judgment

The Council of State fully rejected the Parties' appeals against the TAR Lazio's ruling, which had already entirely upheld the Decision.

Some aspects of the Judgment are particularly notable.

(i) The preliminary reference to the CJEU

The Judgment heavily relies on the guidance provided in January 2018 by the Court of Justice of the European Union ("CJEU") in the interpretative judgment it delivered following a preliminary reference by the Council of State in December 2015.[6]

In response to the preliminary questions raised by the Council of State, the CJEU ruled as follows: (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, when there exists a concrete relationship of substitutability between the authorized and unauthorized drugs; (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 that cannot be exempt pursuant to Article 101(3) TFEU.

(ii) The relevant market definition

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 Judgment rejected this argument. In the Council of State's view, insofar as sector regulation did not forbid 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 drugs typically used for the treatment of eye diseases following a specific marketing authorization and drugs used off-label to treat the same diseases.

(iii) The relationship between the anticompetitive arrangement and the licensing agreement

Regarding the possible significance of a licensing agreement in excluding the existence of collusion between the Parties in violation of Article 101 TFEU, the Judgment upheld the conclusion that in the case at hand the arrangement between the Parties was not ancillary to their licensing agreement.

The Council of State relied in particular on the fact that (as also observed by the CJEU) the disputed restrictive agreement, which included the dissemination of misleading information on the negative side effects of Avastin in case of its off-label use, was not aimed at restricting the Parties' commercial autonomy with respect to Lucentis (which was the product forming the

[6] *F. Hoffmann-La Roche and Others*, C-179/16, EU:C:2018:25.

object of the licensing agreement), but rather the conduct of third parties (in particular healthcare professionals) with a view to reducing the prescription of Avastin in ophthalmology, in order to maximize the economic return on the sales of Lucentis. Accordingly, the agreement between the Parties could not be considered as ancillary and objectively necessary for the implementation of the licensing agreement.

(iv) The dissemination of allegedly misleading information

Finally, the Council of State dismissed the Parties' arguments that the ICA had erred in finding that they had colluded in order "*to manipulate the public's risk 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 eye diseases.

In this respect, the Judgment held that the ICA had based its findings on several pieces of evidence. Accordingly, it was for the Parties to provide alternative lawful explanations for their conduct. In the case at hand, the Council of State held that the Parties had not been able to do so.

In particular, the Judgment dismissed the Parties' arguments that Novartis had an interest in defending Lucentis's sales, whereas Roche had an interest in hindering the off-label use of Avastin in order to limit its own potential liability, as well as possible damage to Avastin's reputation. According to the Judgment, the fact that two competing pharmaceutical companies agreed to disseminate information specifically concerning a medicine marketed by only one of them was an indication that such dissemination pursued objectives other than Roche's compliance with pharmacovigilance obligations and its wish to avoid product liability. The Council of State held that such conduct amounted to a by-object restriction of competition law, aimed at unlawfully partitioning the relevant market.

Other developments

The ICA, the Italian Communications Authority and the Italian Data Protection Authority issue a set of joint guidelines and policy recommendations on Big Data

On July 2, 2019, the ICA, the Italian Communications Authority and the Italian Data Protection Authority (jointly, the "Authorities") issued guidelines and policy recommendations on the digital sector, and specifically on Big Data (the "Guidelines").[7] The Guidelines are the result of a sector inquiry jointly launched by the Authorities in May 2017 and aimed at understanding the potential privacy, data protection, competition and consumer protection implications of the development of the digital and data-driven economy. The Guidelines include a set of guiding principles for the Authorities' future actions in the digital sector (which envisage, *e.g.*, the establishment of "*permanent coordination*" between the Authorities) and policy recommendations for public stakeholders. From a competition law standpoint, recommendations no. 7 and 8 are notable, *i.e.*, (i) the ICA's goal of tackling potential antitrust misconduct by digital platforms by using a framework of analysis which should include reference to objectives such as the quality of services, innovation and fairness; and (ii) a recommendation to public authorities to reform the current merger control system, with a view to enhancing the effectiveness of the ICA's intervention in concentrations carried out in the digital sector.

[7] See "*Big Data. Indagine conoscitiva congiunta. Linee guida e raccomandazioni di policy*", July 2019, a short excerpt of which is available at: https://www.garanteprivacy.it/documents/10160/0/Big+Data.+Linee+guida+e+raccomandazioni+di+policy.+Indagine+conoscitiva+congiunta+di+Agcom%2C+Agcm+e+Garante+privacy.pdf/563c7b0e-adb2-c26c-72ee-fe4f88adbe92?version=1.1.

The Council of State grants the ICA's appeal and reverses the lower court's ruling annulling a 2015 decision concerning an unlawful concerted practice in the railways supply sector among suppliers of goods and electromechanical services for the railway sector

On July 11, 2019, the Council of State set aside a judgment issued by the TAR Lazio in 2016,[8] which had annulled an ICA decision fining Firema S.p.A. ("Firema") approximately €230,000 for its participation, together with 12 other undertakings, in a single and continuous infringement by object consisting of a secret concerted practice in the context of 24 tender procedures for the purchase of goods (mostly coils for electric traction motors) and electromechanical services (mostly repair and maintenance of those engines) for the railway sector called by awarding authority Trenitalia S.p.a.[9]

The Council of State quashed the TAR Lazio judgment on two grounds. First, it held that the fact that Firema's parent company had not been formally involved in the ICA's investigation did not result in its final decision being unlawful, since the parental liability presumption cannot be interpreted as obliging a competition authority – where a company's personal liability for an antitrust infringement is fully established – to subjectively extend an investigation to its parent company. According to the Council of State (whose position does not seem entirely well-founded), pursuant to an established EU case law,[10] the involvement in antitrust proceedings of both a parent company and its subsidiary (which falls within a competition authority's discretion) determines a joint liability for the misconduct at issue, which in turn gives rise to joint and identical accountability for the payment of the fine, regardless of whether the parent company was involved or not in the investigation. Second, the Council of State held that, although for a portion of the overall duration of the infringement Firema was managed by a special administrator (due to the opening of an insolvency procedure), this did not automatically result in the impossibility to attribute the subsequent collusive conduct to Firema, absent a true change in the company's management. Moreover, the fact that such conduct had been carried out by employees "*belonging to the previous management*" was not relevant, in light of the case law by which a company may be liable for antitrust misconduct carried out by its employees even where they lack power of representation.[11]

[8] Council of State, judgment No. 4874/2019.

[9] ICA decision of May 27, 2015, No. 25488, Case I759, *Forniture Trenitalia*. The appeals lodged by some of the other companies fined by the ICA were all rejected by the TAR Lazio: see TAR Lazio, judgments No. 2668, 2670, 2671, 2672, 2673, 2674, 3075, and 3078/2016 (see also Council of State, judgment No. 4211/2018).

[10] *Pirelli & C. v Commission*, T-455/14, ECLI:EU:T:2018:450, § 72 ; *Villeroy & Boch v Commission*, C-625/13 P, ECLI:EU:C:2017:52, §148.

[11] Council of State, judgment No. 5864/2009.

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