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Italian Competition Law Newsletter

Highlights

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On May 17, 2022, the Italian Competition Authority (the "**ICA**") imposed a fine of €3,501,020 on Leadiant Biosciences Ltd. and Essetfin S.p.A. (jointly "**Leadiant**") for violating Article 102 TFEU by charging excessive prices for the sale to the Italian National Health System (the *Sistema Sanitario Nazionale* or "**SSN**") of a drug used for the treatment of Cerebrotendinous xanthomatosis ("**CTX**"), a rare condition that affects the human body's ability to metabolize cholesterols.[1]

After a four-year investigation, the ICA found that Leadiant was dominant in the Italian market for the drugs used to treat CTX with its Chenodeoxycholic Acid (the "**Leadiant CDCA**"), and that it abused its market power by engaging from June 2017 in a complex strategy that was ultimately aimed at creating the most adequate conditions for effectively deploying an excessive pricing policy.

Factual Background

In 2008 Leadiant acquired from another manufacturer a CDCA-based drug ("**Xenbilox**"), which had initially been registered for the treatment of gallstones, but had later been used almost exclusively off-label for the treatment of CTX. The acquisition made Leadiant the only active player at the European level in the commercialization of the drug. The same year Leadiant also entered into an exclusive supply agreement with the only European supplier of Xenbilox's active ingredient. In 2014, Leadiant decided to apply for an orphan drug designation[2] and marketing authorization for its CDCA-based drug for the treatment of CTX.

It then started to significantly increase the price of Xenbilox (from €660 to €2,900 per pack).

[1] ICA, Decision of May 17, 2022 No. 30156, A524 – *Leadiant Biosciences/Farmaco per la cura della Xantomatosi cerebrotendinea* (the "**Decision**").

[2] 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.

In 2016, Leadiant entered the Italian market, where, until then, the supply of Xenbilox had been guaranteed by hospital oncology pharmacies, which had been producing the product themselves in order to provide it free of charge to all patients suffering from CTX. Thanks to the abovementioned exclusive supply agreement, Leadiant was able to prevent Italian hospital pharmacies from finding on the market the active ingredient necessary for the production of the drug. 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 to the Italian CDCA-based drug market.

In June 2017, Leadiant launched in the Italian market the Leadiant CDCA, which was in fact identical to Xenbilox in chemical and pharmaceutical terms, but had a different therapeutic indication. Leadiant started negotiating the price of Leadiant CDCA with the Italian Medicines Agency (the *Agenzia italiana del farmaco* or "**AIFA**"), proposing 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, regardless of 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 SSN to provide patients with an essential, irreplaceable and life-saving drug within a reasonable timeframe and at an economically sustainable price.

As a result, Leadiant was able to obtain a price for its orphan drug of €[*5,000-7,000*] per pack.

The ICA's Findings

The Decision established that Leadiant applied a complex abusive strategy by: (i) increasing the price of Xenbilox (its cheaper drug with the same active substance as Leadiant CDCA 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 excessive prices; and (ii) artificially differentiating between Xenbilox and Leadiant CDCA, with a view to preventing AIFA from gathering information regarding Xenbilox, which Leadiant considered to be irrelevant since the product was not marketed in Italy and, regardless of its off-label use, was indicated for a different therapeutic use (to dissolve cholesterol gallstones). Leadiant achieved such artificial product differentiation through the withdrawal of the first drug from the market when the second one was introduced and by assigning the ownership of Leadiant CDCA to a company specifically set up for the only purpose of being the owner of the off-label drug.

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, with the aim of gaining an undue economic advantage.

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.

In addition, the ICA found that the infringement was still ongoing at the time of the adoption of the Decision, which led it to order Leadiant to take all necessary measures to set for the product prices that were not unjustifiably high and to refrain in the future from engaging in similar conduct.

Regarding the seriousness of the infringement, the ICA noted that Leadiant had intentionally carried out its conduct, imposing exorbitantly high and unfair prices in relation to a drug with no therapeutic alternatives, intended for the treatment of an extremely rare and deadly disease. The ICA therefore categorized Leadiant's abuse as "*extremely serious*". In particular, to set the amount of the fine, the ICA started from a rather high

percentage of the value of CDCA Leadiant's sales in Italy in 2021 (*i.e.*, [20-25%], against a statutory maximum of 30%) and even added a so-called entry fee of [20-25%] of the abovementioned value in the calculation. All in all, once also the duration of the abuse had been taken into account, the fine imposed on Leadiant resulted to be greater than its sales of CDCA Leadiant in Italy in 2021.

Other developments

ICA accepts commitments in investigation into price comparators and insurance companies for alleged collusion on motor vehicle insurance policies

On May 10, 2022, the ICA accepted and made binding the commitments offered by the parties in an investigation concerning an alleged exchange of information in the direct sales of motor vehicle insurance policies. The alleged exchange took place between Italy's leading companies offering price-comparison services (the "**Comparators**") and 13 insurance companies (the "**Insurance Companies**") and intermediaries (the "**Intermediaries**"; jointly, the "**Parties**").[3]

In its decision to open the investigation,[4] the ICA had taken the view that the Parties constantly and regularly exchanged sensitive information on the economic conditions for the sale of motor vehicle insurance policies. Such exchanges allegedly took place through the regular distribution, mostly on a daily or weekly basis, of reports prepared and distributed by the Comparators, containing information regarding, *inter alia*: (i) the premiums of the policies listed on their Internet websites, (ii) the positioning of the Insurance Companies on these websites, and (iii) the data of consumers who had made the requests for a quotation. The ICA suspected that the alleged information exchange was aimed at enabling Insurance Companies to charge final consumers higher premiums for motor vehicle insurance policies by applying lower discounts, due to the mutual knowledge of their respective commercial strategies and pricing policies, in violation of Article 101 TFEU.

In the course of the investigation, the ICA reclassified the alleged restriction of competition as a restriction by effect, rather than by object. The ICA asserted that the data exchanged, by nature and type, served a variety of purposes in the Parties' commercial policies, including that of enabling the participants to offer more attractive commercial terms to customers, and was not aimed solely at setting higher premiums.

In order to address the competition concerns raised by the ICA in its decision to open the investigation, the Parties submitted joint commitments, including:

i. limiting the content and frequency of the reports provided by the Comparators to the Insurance Companies, e.g., by not including information identifying the quotation or the user requesting it; by anonymizing and aggregating information regarding premiums offered by the Insurance Companies and the Intermediaries through the Comparators; and by transmitting such data no more frequently than weekly, in relation only to quotations of at least three months before;

ii. not using reporting services that provided for ways of processing and/or circulation of information that were not compliant with the criteria under (i); and

iii. making the reports provided by the Comparators accessible to the generality of insurance companies and intermediaries, including those not active on the Comparators' websites, at their respective request, on fair and non-discriminatory terms.

[3] ICA, Decision of May 10, 2022, No. 30150, Case I856 – *Comparatori di prezzo/scambio di informazioni polizze RCA*.

[4] ICA, Decision of May 11, 2021, No. 29658.

In the ICA's view, the set of commitments proposed by the Parties was adequate to remove its initial concerns. The ICA therefore made the commitments binding on all the Parties.

In particular, according to the ICA, the commitment that prevents the Comparators from sharing information that identifies the quotations, or the users who requested them, reduces the risk that the Insurance Companies may become aware of the pricing criteria applied by their competitors. The aggregation and anonymization of offers will prevent the identification, by the recipients of the reports, both of the best price (as well as the second and third best prices, as applicable) and of the worst price, as well as of the identity of the company that proposed them.

Council of State judgments on bid-rigging in a tender procedure for the award of facility maintenance services

On May 9, 2022, the Council of State delivered three judgments in annulment proceedings brought by the addressees of a 2019 ICA decision, which found 19 companies liable for participating in a cartel aimed at rigging a tender procedure in the facility maintenance sector in Italy (the "**Decision**").[5]

Background

On April 17, 2019, the ICA found that 15 companies[6] allegedly participated in a cartel that affected the outcome of the so-called "*Facility Management 4*" tender procedure for the provision of cleaning and maintenance services for public offices throughout Italy.

The ICA found that the four main market players led a number of distinct special-purpose temporary associations of undertakings – so-called "*ATIs*" (*i.e.*, *associazioni temporanee di imprese*) – that exchanged information about their bidding strategies during meetings. These exchanges were part of a concerted practice by which the ATIs submitted bids that never overlapped, so as to display a so-called "*chessboard*" pattern. In the ICA's view, further similar information exchanges among the four undertakings took place through subcontracting and consortia.

The ICA concluded that the conduct of the investigated companies constituted a hardcore restriction of competition under Article 101 TFEU, and fined them approximately €235 million overall.

Leniency applicant C.N.S. *Consorzio Nazionale Servizi Società Cooperativa* ("**CNS**") was granted a 50% reduction in its fine.

The judgments of the TAR Lazio

At first instance, the TAR Lazio quashed the Decision to the extent that it was addressed to Engie Energy Services International SA and Engie Servizi S.p.A. (together referred to as "**Cofely**") and Consorzio Stabile Energie Locali S.c.a.r.l. ("**CSEL**"). According to the Court, there was no significant evidence supporting the finding that CSEL and Cofely had jointly participated in the tender with collusive purposes in the context of an ATI), and in fact a sufficient number of elements in the casefile showed that they intended to bid competitively and lawfully.[7]

With respect to the remaining 12 other applicants, however, the TAR Lazio upheld the finding of infringement, and merely ordered the ICA to re-determine the fines originally imposed on all of them.[8]

[5] Council of State, Judgment Nos. 3570, 3571 and 3572 of May 9, 2022.

[6] Namely, C.N.S. - Consorzio Nazionale Servizi Società Cooperativa; Consorzio Stabile Energie Locali S.c.a.r.l.; Engie Servizi S.p.A., jointly and severally with its parent company Engie Energy Services International SA; Exitone S.p.A., jointly and severally with the company Gestione Integrata S.r.l. and with its parent companies STI S.p.A. and Finanziaria Bigotti S.p.A.; Kuadra S.r.l., jointly and severally with its parent company Esperia S.p.A.; Manital Società Consortile per i Servizi Integrati per Azioni Consorzio Stabile - Manital S.c.p.a., jointly and severally with its parent company Manitalidea S.p.A.; Rekeep S.p.A.; Romeo Gestioni S.p.A. jointly and severally with its parent company Romeo Partecipazioni S.p.A.

[7] TAR Lazio, Judgment Nos. 8765, 8767 and 8768 of July 27, 2020 (discussed in the July 2020 issue of this Newsletter: https://www.clearygottlieb.com/-/media/files/italian-comp-reports/italian-competition-law-newsletter-july-2020.pdf).

[8] TAR Lazio, Judgment Nos. 8762, 8769-8772, 8774-8779 and 8781 of July 27, 2020 (discussed in the July 2020 issue of this Newsletter: https://www.clearygottlieb.com/-/media/files/italian-comp-reports/italian-competition-law-newsletter-july-2020.pdf).

The Council of State's rulings

The Council of State delivered three sets of judgments.

Upholding the TAR Judgment

The Council of State fully confirmed the TAR Lazio's rulings – and thus the ICA's finding of infringement – in relation to 7 companies (namely, Rekeep S.p.A., Romeo Gestioni S.p.A., Exitone S.p.A., Finanziari Bigotti S.p.A., Gestione Integrata S.r.l. and STI S.p.A.).

The Council of State also upheld the TAR Lazio judgments with regard to Cofely and CSEL, thus confirming that the Decision was manifestly unfounded as far as these undertakings were concerned. It held that the economic and technical offers submitted by Cofely and CSEL were inherently aggressive and overlapped with the bids submitted by the cartelists, confirming in addition that there was no evidence of any kind of a collusive agreement between the two companies and the other participants to the alleged cartel.

Overturning the Decision in relation to 4 applicants

With respect to four further companies (namely, Manital S.c.p.a. and its parent company Manitalidea S.p.A.; and Kuadra S.r.l. and its parent company Esperia S.p.A.), however, the Council of State set aside the TAR judgments and, thus, annulled the Decision. According to the Court, Manital provided reliable alternative justifications for its bidding behavior, supported by evidence. In particular, Manital proved that it was awarded the tender offers based on technical reasons and that its contested conduct was justified by economic continuity (*e.g.* it submitted offers for lots where it was the outgoing service provider) and turnover limitations (*i.e.* it could not have submitted more offers). On the other hand, the Council of State stated that the evidence collected by the ICA regarding Kuadra was ambiguous and insufficient to demonstrate its participation in the cartel.

Reduction of the fine imposed on the leniency applicant

Finally, with respect to CNS – which challenged the Decision to grant it a mere 50% reduction in the fine, instead of total immunity – the Council of State ordered the ICA to re-determine the fines originally imposed to take account of the fact that the statements and documents produced by CNS as part of its leniency application constituted the most significant evidence used by the ICA to support its finding of an infringement of Article 101 TFEU.

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