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### I. Introduction

The Argentine government has implemented price and supply controls over health-related and mass consumption products to protect consumers in the wake of the COVID-19 pandemic.

Said measures have gone hand in hand with a strong enforcement of competition laws, aimed to prevent and/or sanction abuses of dominance. In line with this, the Argentine government has recently entrusted to the competition authority the opening of an in-depth investigation to analyze potential exploitative abuse in the pharmaceutical industry on the grounds of "excessive pricing."

It remains to be seen whether the competition authority will take this investigation as an opportunity to fully understand, analyze, and come up with a strong technical-legal test to rule out excessive pricing abuses. Alternatively, the investigation could be deployed as a tool to put pressure on the parties during the investigation, gather sensitive and confidential information, and end up – after some years – archiving the docket or accepting certain commitments to lower or maintain prices.

# II. The Measures Adopted by the Argentine Government to Manage the New Normality: Price and Supply Controls in Argentina

Since March 2020, the Argentine government has been taking numerous measures against the COVID-19 pandemic. To mitigate the economic effects of the crisis on consumers, price and supply-levels controls have been put in place. These types of measures have also been adopted in other parts of the world in light of the pandemic (e.g. Canada, United States, Germany, Greece, Italy, France, India, Japan, among others), with different scopes and modalities.<sup>2</sup>

The measures adopted in Argentina deeply affect business freedom and property rights, protected under the Argentine Constitution. Said restrictions, however, have been put in place temporarily and in the wake of the pandemic, so they could reasonably pass a constitutional test challenging their legality.

That said, control and supply measures operate within a challenging macroeconomic environment for Argentine companies: annual inflation rate of around 40 percent (approx. 3-4 percent per month), unemployment rate reaching about 10 percent, economic depression (2020 GDP loss 8 percent), and an economy that presents serious imbalances in the commercial chain and consumer prices.

To protect consumers, price and supply controls include essential products linked to public health (e.g. medical supplies, face masks) and others of an essential nature (food, hygiene, personal care). These measures have been in-force since March 2020 to date, but given the inflationary context, the government has begun to authorize companies to slightly increase the prices of certain products.<sup>3</sup>

# III. Recent Price and Supply Controls in the Pharmaceutical Industry

On June 30, the Domestic Trade Secretary ("SCI") issued Resolution 202/2020, which applied price and supply control over a product commercialized by Biogen Argentina, which

is an important player in the pharmaceutical industry and is also a supplier to the National State.

The measure set the maximum sale price of an active ingredient ("Nusinersen (Spinraza®) 12mg/5mL," at a value equivalent to USD 27,000. In practical terms, this is a discount of about USD 100,000 from the price suggested by the company. In addition, the resolution also requested the company, in its capacity as importer of the active ingredient, to ensure the provision and marketing of "Nusinersen (Spinraza®) 12mg/5mL."

Lastly, the SCI entrusted the local competition authority (National Commission for the Defense of Competition ("CNDC"), to open an in-depth investigation into this market, to rule out possible violations of the Competition Law No. 27,442 ("LDC").

# IV. What Can be Expected from the Argentine CNDC Regarding Price Controls?

Price and supply control measures have been, in their great majority, issued by the SCI. This Secretary acts under the orbit of the Ministry of Productive Development, which is part of the National Executive Power.

The SCI contains the CNDC within its organizational chart. The CNDC is a technical body that lacks decision-making power (for the application of sanctions), which corresponds to the Secretary to whom it reports.

This is not the first time that the SCI entrusts the CNDC to carry out market investigations, even in the wake of the pandemic (e.g. beef market and liquid oxygen market investigations). What is interesting, though, from a competition law perspective, is the expectation that the SCI could have out of the analysis to carried out by the CNDC in the *Biogen* case.<sup>4</sup>

The resolution issued by the SCI that orders the CNDC to open the investigation lays down the following: (i) this is a concentrated market, dominated by Biogen; (ii) the price of the product would have been unreasonable and abusive for not responding to its structure of costs or at comparable prices in the region; and (iii) that "disproportionate profits" would have been obtained from sales of the product.<sup>5</sup>

This appears to be a new case of "abusive" or "excessive" pricing, which immediately brings to our memory the recent CNDC case-law In re "SADAIC" (2019).<sup>6</sup> In that case, the CNDC sanctioned, for the first time, the imposition of abusive prices.

Although the decision was partially set aside by the Court of Appeals, it provided valuable insights as to when the competition authority may consider an abusive price as anticompetitive. In other words, what particularities could legitimate "price controls" measures from the competition authority.

# A. Brief approach to the "SADAIC" case

In October 2009, the Gastronomic Hotel Business Federation of Argentina ("FEHGRA") filed a complaint against the Society of Authors and Composers of Music ("SADAIC") for the modification of its tariff scheme, which caused an increase in the fees charged to the hotel sector for the use of musical works.

More than 7 years after the complaint, in May 2017, the CNDC decided that SADAIC set abusive tariffs, excessively high in comparison, both with those in force in several Latin

American countries and with those charged by other collective copyright management entities operating in Argentina.<sup>7</sup>

The CNDC also took into account that: (i) SADAIC enjoyed a dominant position in a monopoly market; (ii) the market showed no specific regulation (the legal framework does not provide for the secondary reproduction of music in hotel establishments); (iii) the new rate schedule involved discriminatory practices against higher-income hotels and against those who had not signed certain agreements with SADAIC; (iv) prior to the rate increase, the rates were already very high.

In 2018 the SCI adhered to the CNDC's opinion, and concluded that the actions of SADAIC have been in breach of the Argentine competition law. Therefore (i) it condemned the payment of a fine of ARS 42,732,771 (approx. USD 1,500,000 at that time); and (ii) recommended to the Executive Branch to establish a new regime for setting tariffs, and that it modernize the collection management system and review the tariff tables applicable to users who carry out public works execution. It was also stressed that the disparity of tariffs or their accumulation, can have an unreasonable impact on economic activity.

This decision was partially revoked: The Court of Appeals rejected the fine imposed, but confirmed the need for the Executive Power to issue a regulation establishing the guidelines that the setting of tariffs should contain.<sup>8</sup>

The Court of Appeals analyzed the reasonableness of the new rate schedule and concluded that there was no evidence of harm to the general economic interest, which is precisely what the LDC aims to protect.

The LDC protects the consumers ´ welfare indirectly: The power of the CNDC to sanction abuses of a dominant position does not enable it to exercise direct control of prices, but only through indirect regulation mechanisms.

In light of the above, the Court of Appeals concluded that (i) the application of sanctions must be interpreted restrictively, based on clear evidence of an effective limitation on competition; (ii) it cannot be concluded that there is an abusive price based on comparing the fees charged in Argentina with those charged by other countries in the region; (iii) the price that the CNDC could consider excessive does not constitute an anti-competitive conduct *per se*; (iv) the SCI should have ordered to stop with the conduct, or to establish the tariffs or equilibrium prices, instead of applying a fine and issuing recommendations to the Executive Branch.

# B. New legal test for "Excessive Pricing" in the wake of the pandemic?

As in other parts of the world, the issue of excessive pricing in Argentina is a delicate, highly discussed and very much exposed to public scrutiny. In a country with strong macroeconomic imbalances, the impact of prices on consumers is a priority for public officials. Thus, price-related investigations could be ignited by political sentiments.

Resolution SCI 202/2020 ordered the CNDC to open an in-depth market investigation into Biogen, to determine whether the price of one of its products would have breached competition law. There may be two preliminary characteristics that differentiate this investigation from previous ones, including the leading case "SADAIC": It involves the pharmaceutical industry, and that it emerges in the context of the pandemic, where the preservation of public health a policy of the State. Abusive prices are not expressly defined in the LDC. But this is not an obstacle for the CNDC to investigate and consider them as anticompetitive, provided that there is a harm to the general economic interest. In fact, that was the approach that was taken by the CNDC to build its case in "SADAIC."

Per the "Guidelines for the Analysis of Cases of Abuse of Dominant Position of Exclusionary Type" issued by the CNDC, excessively high prices constitute an exploitative abuse that fall under the orbit of the abusive behaviors pursued by LDC. Said conducts are prohibited and are a punishable abuse of dominance, insofar as they harm the general economic interest.

The SCI and the CNDC know the pharmaceutical industry very well, because it has been one of their main focuses of attention in recent years. In 2017, a market analysis concluded that no merits were found to open an in-depth investigation.<sup>9</sup>

Nowadays, the SCI and the CNDC are thoroughly analyzing and crossing data (namely, prices versus costs), based on the information gathered from those companies that are subject to price controls. It could reasonably be expected that the CNDC will analyze excessive pricing in light of Biogen's costs, prices and the restrictive criteria established in "SADAIC."

Attention should also be paid to whether the CNDC draws on its analysis of parameters constructed in foreign case-law. For example, in the *United Brands* case, the European Court of Justice ("ECJ") constructed a test to evaluate abusive prices.<sup>10</sup> It held that a price can be considered excessive when "*it does not have a reasonable relation with the economic value of the product supplied*" (see paragraph 250 of the ECJ judgment). Closer in time, in 2016, the UK Competition and Market Authority ("CMA") analyzed and sanctioned the prices charged by Pfizer and Flynn, in relation to certain pharmaceuticals.<sup>11</sup> Although the CMA's decision was set aside by the Court of Appeals in respect to the existence of abusive price, it provided a careful analysis of the interpretative intersection between the *United Brands* test and the economic analysis made by the CMA.<sup>12</sup> At the European level, in 2017 an investigation was opened against the South African-based pharmaceutical company Aspen Pharma, due to possible excessive prices for certain vital cancer drugs. A few days ago, the European Commission invited all interested parties to comment on Aspen Pharma's commitment to lower its prices.<sup>13</sup>

It remains to be seen whether the CNDC introduces into its analysis the price regulation factor in the pharma industry (following the criteria set forth in "SADAIC"). The CNDC has powers to issue a request for information to the relevant agency (National Administration of Drugs, Foods and Medical Devices ("ANMAT")). The CNDC could also aim to investigate and analyze when a given price is reasonable or not, if the prices are comparable at the regional level or if the profits gained by Biogen have been disproportionate, as suggested in the Resolution SCI 202/2020.

The CNDC confronts with the arduous task of removing the restrictive criterion that prevails to sanction excessive prices. In this context, the knowledge of the pharmaceutical sector acquired after the 2017 market analysis, the granular concepts laid down In re "SADAIC," and the foreign case-law could be important. At the end of the day, the CNDC will aim to unveil when a freely fixed price strays so far from its cost structure, that it becomes an abuse of a dominant and exploitative position, causing harm to consumers.

#### V. Conclusions

The Argentine government is resorting to all kinds of economic legislation tools to mitigate the effects of the economic crisis, and to assure consumers reasonable and equitable levels of prices and supply of essential inputs to live through the pandemic.

Emergency regulations have empowered the government to set maximum prices and dictate measures to guarantee supply. This especially includes access and affordability of those goods or services that involve the population's health.

Legal counsels should be aware that competition law enforcement in Argentina, in the wake of the pandemic, remains very strong. Notably, if the matter has to do with prices and involves pharma products. Political sentiments may ignite competition law investigations. It remains to be seen whether the CNDC constructs a proper legal test for excessive pricing, that could eventually be upheld at a court level.

<sup>2</sup> Tackling the COVID-19 challenge—a perspective from the CMA, available at <u>https://academic.oup.com/antitrust/article/8/2/250/5856299</u>.

- <sup>6</sup> Resolution SCI 371/2018 and Decision CNDC 43/2017 issued within the Docket No. S01: 0427368/2009 (C. 1302) titled "Federación Empresaria Hotelera Gastronómica de la República Argentina S/ Solicitud de intervención de la CNDC (C. 1302)."
- <sup>7</sup> Resolution SCI 371/2018 and Decision CNDC 43/2017 issued within the Docket No. S01: 0427368/2009 (C. 1302) titled "Federación Empresaria Hotelera Gastronómica de la República Argentina S/ Solicitud de intervención de la CNDC (C. 1302)."
- <sup>8</sup> Federal Court of Appleals in Civil and Commercial Matters, Docket No. 7971/2018/CA1 titled "Federación Empresaria Hotelera Gastronómica de la República Argentina c/ SADAIC y otro s/ apel. res. Comisión Nacional de Defensa de la Competencia."
- <sup>9</sup> Docket No. EX-2017-15555021-APN-DDYM#MP titled "INVESTIGACIÓN DE MERCADO SOBRE LAS CONDICIONES DE COMPETENCIA EN EL MERCADO DE MEDICAMENTOS (IM 4)."
- <sup>10</sup> Judgment of the ECJ dated February 14, 1978 In re "United Brands Company and United Brands Continentaal BV v. Commission of the European Communities," [1978] ECR 207.

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<sup>&</sup>lt;sup>3</sup> Resolution 13/2020 issued by the Subsecretariat of Consumer Protection of Argentina on July 15, 2020.

<sup>&</sup>lt;sup>4</sup> In March 2020, the SCI entrusted the CNDC to open an in-depth investigation into the beef market, to determine the possible commission of breaches to the LDC (Art. 7, Res. SCI 103/2020). Also, according to a press release published on April 29, 2020 on the Ministry of Productive Development's website, the CNDC will open a new investigation of the market for bulk and tube medicinal liquid oxygen, alongside its transportation service, to determine possible breaches to the LDC.

<sup>&</sup>lt;sup>5</sup> Resolution 202/2020 issued by the Secretary of Domestic Trade on June 30, 2020.

<sup>&</sup>lt;sup>11</sup> UK CMA decision of February 12, 2016 in Case CE-9742–13 Phenytoin Sodium Capsules.

<sup>&</sup>lt;sup>12</sup> [2018] CAT 11. Case N: 1275-1276/1/12/17.

<sup>&</sup>lt;sup>13</sup> Press release available at <u>https://ec.europa.eu/commission/presscorner/detail/en/ip\_20\_1347</u>.