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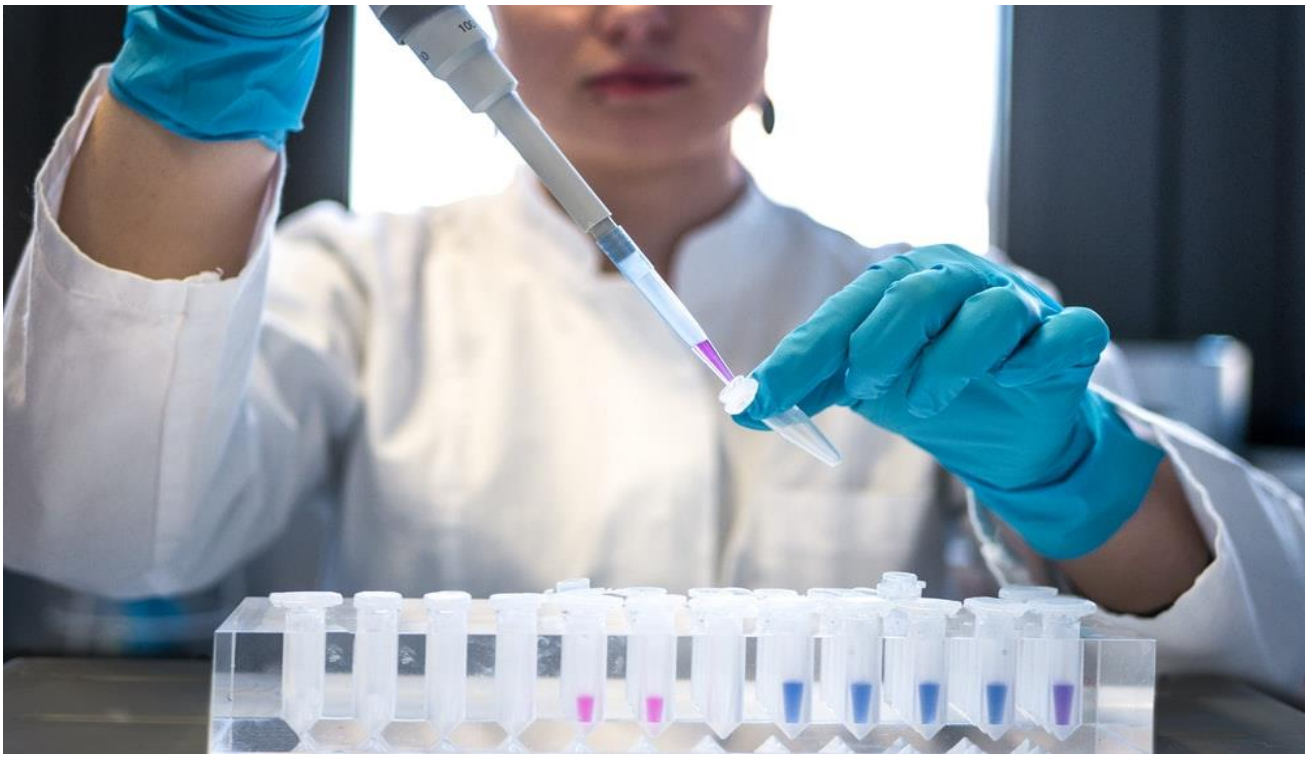

Dear all,

We are happy to kick off spring with a new release of our Healthcare & Competition newsletter, which we slightly rebaptized in order to cover connected and interrelated industries (pharma, medical devices, cosmetics, etc.)

Many antitrust decisions and ongoing investigations deserve a close look. They are full of new approaches and adaptations to new realities: misuse of patent procedures and disparaging communication campaigns as abusive conducts; reduction of price and maintenance of price ceilings as accepted commitments during long periods of time in excessive pricing cases; and public procurement restriction cases which are still very much the target of antitrust enforcers.

We try to give you a hint on those ongoing investigations and also finish the Newsletter with several short highlights that may deserve a closer look in the near future.

Enjoy!

Competition law Team, Marimón Abogados

First EU case of misuse of patent procedures and smear campaigns

The European Commission opened formal antitrust proceedings against Teva for possible abuse of a dominant position concerning the commercialization of its flagship drug Copaxone for the treatment of multiple sclerosis.

The Commission wants to investigate whether the pharmaceutical company had artificially extended the exclusivity period for its drug beyond the expiry of the patent on its active ingredient in 2015, with an aim to delay the entry of competing generic or biosimilar medicines.

The decision follows investigations conducted at Teva's premises on October last year and earlier this year.

The practices under investigation would have consisted in particular of:

(i) Misuse of patent procedures

After the expiry of the "parent" patent, which protected the active ingredient glatiramer acetate, Teva would have strategically filed and withdrawn divisional applications for it. These applications were filed under the pretext of extending patent protection to new discoveries, but in practice they resulted in a large family of patents often covering overlapping inventions. These served to hinder market entry by competitors who were forced to challenge all these multiple patents if they wanted to enter the market.

(ii) The launching of a communication campaign to discredit competing products

The Commission wants to investigate whether the communication campaign launched by Teva aimed at health professionals and centres was intended to hinder the use of alternative generic medicines to Copaxone (e.g. by giving false indications about the risks associated with the consumption of these medicines, even when they had already been authorized by the competent authorities).

This is the first case in which the Commission is investigating potentially abusive practices consisting of the misuse of patent procedures or the discrediting of competing products in the pharmaceutical sector. According to the Commission's press release there is no reference to the abuse having consisted of fraudulent or illegal use of the patent system, but only to a mere 'misuse' which might not correspond to an infringement of IP rules.

The case obviously bears some resemblance with the EU ITT Promedia (case T-111/96) and AstraZeneca (cases T-321/05 and C-457/10) doctrine on abuse of regulatory procedures, where the discussion concerned the anticompetitive misuse of administrative and judicial procedures with misleading information involved. The connection with sham litigation and the Spanish MSD case of which we informed in prior newsletters seems also evident, but we will have to wait for the investigations to progress for further details.

Harm to the public sector as an aggravating factor in competition penalties

On 2 February 2021, the Spanish Competition Authority (the "CNMC") imposed a total fine of 5,7 million euros on the pharmaceutical companies Advanced Accelerator Applications Iberia ("AAA") and Curium Pharma ("Curium") and Novartis and Glo Holdco, as their respective parent companies, for the creation of a cartel for the supply of PET radiopharmaceuticals that lasted more than 4 years.

Background of the case

These companies -which control almost 100% of the national market for the supply of PET radiopharmaceuticals to public and private hospitals- reached non-aggression and bid-sharing pacts, concluded cross-supply and price-fixing agreements and exchanged sensitive commercial information. The behaviour was two-fold:

(i) Subcontracting agreements:

Although subcontracting agreements are *a priori* lawful and facilitate access to the market for companies other than those awarded the contract, they can sometimes be problematic, especially when such agreements are not based in an economic rationale.

In the market for the supply of radiopharmaceuticals, the best positioned company is usually the one with cyclotrons closest to the hospital in question. In this case, the sanctioned companies agreed just the opposite. In those hospitals where there could be greater competition, it was agreed that the company that had closest cyclotron would not submit the most advantageous offer and so the other company would be awarded the contract. The winning bidder would then subcontract the service to the company with the closest cyclotrons at a much lower price than the one charged to hospitals.

In this way, the winning bidder obtained profits without compromising its production (which could be used for closer clients) and the subcontracted company obtained part of the profits from the tender.

(ii) Distribution of hospitals for exclusive supply:

Non-aggression pacts materialized through three types of actions: self-exclusions of the bidding process, non-competitive bids and bids excluded due to formal defects that were not remedied.

Fines imposed

- Financial penalties

Penalty rates applied to determine the fines for the companies are strikingly high (i.e. they amount to 7.1% for AAA and 8.9% for Curium of the worldwide turnover of the group to which

each of the companies belong). For its setting, the CNMC considered that the infringement affected public procurement (i.e. 85% of the clients were public clients, which made the products tendered more expensive with the consequent damage to public funds) and the products affected by the cartel were healthcare products. In addition to the penalties imposed on the companies, the general managers of each of the pharmaceutical companies were personally fined for their involvement in the infringement with 46,000 euros.

- Prohibition to contract with the public sector

Likewise, companies were banned from contracting with the Public Administration. The decision does not establish the scope and duration of the prohibition, but it requires the competent authority (the Ministry of Finance after consultation to the Board on Public Procurement; JCCP for the Spanish acronym) to take into account (i) that the facts investigated referred to the health sector; (ii) that the combined market share was close to 100% and (iii) that the business volumes related to contracts with the public sector were close to 85%.

Following the recent trend of recognizing the adoption of self-cleaning measures for the purpose of calculating fines, the CNMC seems to suggest that the adoption of these measures should also be taken into consideration in terms of the exclusion of companies from the prohibition to contract with the public sector.

For a more thorough analysis on these type of public procurement-related sanctions, see our recent Newsletter on this specific topic.

Excessive pricing abuse: the European Commission accepts commitments by Aspen

The European Commission made binding the commitments proposed by Aspen in the framework of the proceedings initiated against the pharmaceutical company for abuse of a dominant position by charging excessive prices on 6 essential drugs for cancer treatment, mainly used to treat leukaemia and myeloma.

Background of the case

On 15 May 2017, the Commission initiated formal antitrust proceedings against Aspen to investigate the pricing practices allegedly carried out by the pharmaceutical company since 2012, when Aspen acquired the 6 relevant medicines from another company. Aspen progressively increased the prices of the medicines in all the European countries where it marketed them, to the point where prices exceeded costs by more than 300% on average.

The Commission considers that the profit made would have been excessive both in absolute terms and in comparison, with the one made by similar companies in the sector. Moreover,

there were no reasons that could justify such prices for drugs whose patents had expired more than 50 years ago (i.e. R&D costs had already been more than recovered). In its preliminary assessment, the Commission maintained that the company had taken advantage of the fact that in most countries where the drug was marketed there was no substitute medicine.

Evidence would show that when national authorities refused price increases imposed by Aspen, the company threatened with drug withdrawal.

Final commitments

The agreed commitments to address the competition concerns highlighted by the Commission are as follows:

(i) to reduce the prices for the 6 medicines across all European countries affected by the practice by 73%, which should correspond to the prices applied before 2012;

(ii) to maintain such price ceilings for a period of 10 years, with an effective start date of 1 October 2019. Aspen is expected to be able to request a review of these ceilings if the costs associated with the manufacture of the medicines increase significantly (i.e. by more than 20%);

(iii) to guarantee the supply of these medicines for a period of 5 years and for an additional 5-year period to either maintain the supply or licence the marketing authorization to other suppliers.

The commitments cover the entire European Economic Area, except Italy, as the *Autorità Garante Della Concorrenza* had already fined Aspen in 2016 for an abuse of a dominant position on the Italian market consisting of the same behaviour.

Other HIGHLIGHTS and FOLLOW-UPs…

- EU and American competition agencies launch pharma mergers working group

On 16 March, the European Commission, the Federal Trade Commission, the US Department of Justice, the Canadian Competition Bureau, the UK Competition and Markets Authority and three offices of Attorneys General launched an inter-authority cooperation project to analyse the effects of mergers in the pharmaceutical sector. The project is expected to provide greater expertise to competition authorities when analysing transactions in this sector and to ensure the most effective enforcement in this sector.

- DG COMP issues comfort letter for a matchmaking event on COVID vaccination and is expected to issue another one in the coming weeks

On 25 March, the European Commission gave its blessing to an online event, co-organized by Ecorys Europe and SPI, to be held on 29 and 31 March and enabling the meeting of more than 300 participants. The aim of the event was to increase the capacities to produce and supply COVID-19 vaccines that are authorised (or in the process thereof) in the EU.

The EC acknowledged that producers of COVID-19 vaccines are facing bottlenecks in many parts of the supply chain, including access to raw materials and other essential inputs and one of the fastest ways to increase production is to engage with companies that already have available and relevant capacities. Provided information exchanges are limited to what is indispensable for effectively resolving the supply challenges linked to COVID-19 pandemic, they shall not raise Article 101 TFEU issues. A record of discussions had to be kept and may eventually have to be shared with DG COMP.

This is (only) the second comfort letter issued since the COVID-19 outbreak and applying the principles contained in the Commission's Temporary Framework published on April 2020. As publicly reported by Commission officials, another comfort letter to allow cooperation in the pharmaceutical sector may follow in the coming weeks…

- Lucentis saga to be continued…

On 23 January 2018 the ECJ ruled that off-label medicines may be competing with authorized medicines for a given disease and, therefore, an agreement between their respective producers could infringe Article 101 TFEU. Although this judgment led the Italian *Consiglio di Stato* to confirm a fine from the Italian Competition Authority, the parties (Hoffmann-La Roche and Novartis) further challenged this decision. As publicly reported, the case was referred again on 21 April 2021 to the ECJ for guidance (case C-261/21 to be closely monitored). On this saga, see also our October 2020 Newsletter on the French side of the case.

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Marimón Abogados is a law firm founded in 1931 that offers legal services in all fields of law and has offices in Barcelona, Madrid and Seville. Our firm has adapted to the changes that have taken place in the legal market, creating specialised departments with extensive experience that accompanying our clients in their daily activities.

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Our Desks




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