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Healthcare & Competition

February 2023

Dear all,

We hope 2023 started very well and brings joy and prosperity for you all.

In this new issue of our Healthcare & Competition Newsletter, we provide an overview of the most relevant news for this sector on the authorities and courts' front. In particular, we revisit the highly controversial Grail/Illumina case which seems to have a promising future in the podium of European competition law sagas.

Also, very specially, we proudly present two cases in which we successfully advised clients on antitrust matters: (i) the first European fine for sham litigation, in which we acted as complainants; and (ii) the conventional termination of a Spanish antitrust file referred to vertical practices.

We will close the Newsletter with several short highlights that may deserve a closer look in the near future.

We wish you a pleasant reading!

Competition law Team, Marimón Abogados

The CNMC fines Merck for abuse of dominance in contraceptives' market

We hereafter proudly present a landmark decision of the Spanish CNMC in a case in which we were closely involved as complainants. It brought *blood, toil, tears and sweat*, and it will certainly bring more. Litigation will surely be fierce and the judicial outcome is uncertain. Be that as it may, the decision is already a cornerstone among competition precedent, as it is the first time ever that sham anticompetitive litigation is effectively fined in Europe.

In 2017, Merck Sharp & Dohme brought patent infringement action against its competitor, Insud Pharma, for allegedly breaching patent rights over Nuvaring, MSD's blockbuster vaginal contraceptive ring.

Interim measures *inaudita parte* were initially granted by a Spanish commercial Court in Barcelona, that effectively prevented Insud Pharma from commercializing its competitor ring, Ornibel, all over Europe. Inasmuch as production premises were located in Spain and interim measures blocked any further production or commercialization in/from Spain, they effectively blocked also the possibility to honour orders coming from other countries.

Subsequently, however, after hearing Insud Pharma, the patent judge revoked interim measures and severely reprimanded MSD for providing misleading and deceptive evidence. Insud Pharma had provided prima facie evidence that its new product, although qualified as a generic for pharmaceutical purposes, did not infringe MSD's patent. Thereafter, Insud Pharma sought damages' compensation for the unfounded interim measures.

In parallel, Insud Pharma also brought the case before antitrust authorities. Following the corresponding complaint, which triggered dawn raids in Merck's premises,[1] on 20 November 2019, the CNMC decided to open an antitrust file against MSD for possible abuse of dominance, grounded on the ITT Promedia and Astrazeneca EU case-law (for further reference, see here).

After an arduous investigation with multiple procedural ins and outs, on 21 October 2022 the Spanish CNMC finally decided to fine MSD €38.9 million for sham litigation. The case is novel and extremely interesting in various aspects (…apart from having us as successful advisors to the complainant…):

- Market definition: the CNMC considers that the relevant market is restricted to vaginal contraceptive rings. The case considers the ATC traditional rationale, but somehow departs from its boundaries considering (i) the particular characteristics of the pharmaceutical product at hand, for which use the preferences of women play a strong role; (ii) MSD's own public documents submitted to the American Securities & Exchanges Commission attributed a major role to generic rings in their sales decrease, whereas it had not been the case with other contraceptive methods.

[1] La CNMC investiga posibles prácticas anticompetitivas en el mercado español de la fabricación y comercialización de medicamentos anticonceptivos hormonales combinados

- Dominance: other than the obvious relation with market definition, dominance is hardly disputed. MSD's market shares for Nuvaring left no room for many doubts…

- Abuse: here is where the case is more revolutionary. Although sham litigation has been fined elsewhere (notably, the United States) and theoretically defined by EU case-law,[2] it had never been declared and fined in our confines. It is, thus, the first time that the boundaries of that case-law are practically perceived. The main issue revolves around the fundamental right to bring judicial action to defend one's rights, regardless of the infimal possibilities of success. In theory, having scarce (or even derisory) chances of success is no reason to find litigation abusive. Such a finding requires more. Clear deception and self-awareness of the unfounded action must be shown.

  Using the terms of EU case-law, two cumulative requisites must be shown: (i) the action must, on an objective view, be manifestly unfounded; and (ii) the action must have been conceived in the framework of a plan whose goal is to eliminate competition. If the first criterion is already difficult and probably requires some sort of explicit judicial reprimand as it existed here (see here), the second one may be in most cases unattainable. A company will not normally air its own unspeakable purposes, nor even report them internally. The fact that the CNMC apparently found internal documents to this effect during the dawn raids may be one of the rarest exceptions to confirm the rule…

The case will surely bring succulent judicial debate. Courts will likely be extremely strict with the CNMC, as limiting access to justice may seem too burdensome a consequence of antitrust rules even for dominant companies. The CNMC is aware of this and carefully reasons in its decision that it limits the finding to the sphere of patent litigation, where also exceptional routes of action are foreseen for patent holders. We will have to wait and see if the reasoning meets the mind of judges. We will keep you posted.

CNMC closes the file against ISDIN by conventional termination

On 26 October 2020, the CNMC opened an antitrust file against the Spanish pharmaceutical company ISDIN, after receiving a complaint from an operator engaged in the distribution and marketing of over-the-counter (OTC) pharmaceuticals and personal hygiene products as well as body and healthcare products.

The CNMC took initially some time trying to verify the claims included in the complaint and asking third parties about their own experience with ISDIN. It was primarily checking

[2] See ITT Promedia (case T-111/96), AstraZeneca (cases T-321/05 and C-457/10) or Agria Polska (case T-480/15).

whether the company could have implemented vertical price-fixing and/or online discrimination practices regarding the retail marketing of sun care products.

ISDIN requested the conventional termination of the procedure, by submitting a series of commitments intended to resolve any competition problems detected.

Conventional termination is an atypical means of closing an antitrust file,[3] by enforcing voluntary commitments offered by the alleged infringer, thereby avoiding any declaration of infringement and/or fine. Conventional termination is adequate when evidence of an alleged infringement may be dubious or controversial, and the hypothetical harm to competition can be redressed with behavioural changes from the undertaking concerned.

On 30 November 2022 the Council of the CNMC validated the proposal and closed the file subject to compliance with the aforesaid commitments. Very briefly, commitments consist mainly of (i) implementing an objective, transparent and non-discriminatory price policy among pharmacies and other distributors; (ii) fostering an internal culture of compliance with competition rules, establishing an early warning system and specific training sessions; and (iii) technologically impeding the commercial team access to detailed information on retail sales prices.

The Resolution is great news for the company (and us, as their legal advisors…!) as it was undoubtedly a unique opportunity for conferring robustness on ISDIN's commercial practices and compliance protocols.

Besides, we cannot help mentioning that the Resolution comes timely after the approval of the new Vertical Block Exemption Regulation and Vertical Guidelines.[4] These new rules radically changed the approach of competition authorities vis-à-vis online commerce (notably, dual pricing is no longer an issue under antitrust rules!) and, thereby, made it arguably quite difficult for the Spanish authority to potentially defend a case based on such hypothetical infringement…

Excessive pricing of orphan drug is abusive, CNMC says

Antitrust regulators are not keen on excessive pricing cases. They are not supposed to act as price setters and they are, thus, unease when having to evaluate retrospectively how much previous R&D efforts were worth and whether they justify a certain price of a laboratory. However, there are certain cases where antitrust regulators cannot, or so they say, *laisser passer*… Cases as the European Aspen precedent,[5] where prices rose so much in a given

[3] Article 52 of the Spanish Act on the Defence of Competition.
[4] Commission Regulation (EU) 2022/720 of 10 May 2022 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of vertical agreements and concerted practices and Guidelines on Vertical Restraints (2022/C 248/01) setting out the principles for the assessment of vertical agreements under Article 101 of the Treaty on the Functioning of the European Union.
[5] Competition Policy

period and in relation to markets where competition neither exists nor is it expected, that no competitive justification seems admissible.

The Leadiant set of cases is another example. Fined already in the Netherlands[6] and Italy,[7] it is now the Spanish CNMC that fined the same company for the same behaviour. The three regulators found that the company charged their respective national health systems (NHS) unfairly excessive prices for the sale of a life-saving drug.

As regards the Spanish case, on 14 November 2022, the CNMC fined Leadiant with a € 10,25 million[8] for abusing its dominant position, through the imposition of excessive prices in the market for the manufacture and supply of medicines using chenodeoxycholic acid (CDCA) for the treatment of an ultra-rare hereditary metabolic disease called cerebrotendinous xanthomatosis (CTX).

For decades, the illness had been treated with drugs containing CDCA as the active ingredient. The CNMC considers proven that since 2007 Leadiant developed a whole strategy in order to (i) first, gain exclusivity in the commercialization of CDCA-based drugs; and (ii) thereafter, withdraw, reformulate and rebrand certain drugs in order to increase the price over 14 times. The average cost of the treatment was around €1000/package in 2020 and escalated over €14,000/package in 2017.

As in any excessive pricing case, the main difficulty is finding a relevant comparator against which one can assess excessiveness. The CNMC's analysis establishes, firstly, an excessive disproportion between the risks and the costs actually borne by Leadiant for the development and marketing of its rebranded drug and the price actually charged in Spain. Secondly, the CNMC's considers that the price is not fair in itself in terms of its economic value. Whereas Leadiant had claimed that the rebranded drug offered significant advantages over its predecessors, the CNMC found no significant added value given the considerable lapse of time that CDCA-based drugs had been previously commercialized safely and effectively.

The final amount of the fine is set at €10.25 million and the company is mandated to negotiate a new price with the Spanish NHS. Interestingly enough, the CNMC also considers imposing a ban to tender in public bids, but if finally discards the option as, in the absence of competition, such a ban would very much prejudice the NHS and patients themselves.

[6] ACM imposes fine on drug manufacturer Leadiant for CDCA's excessive price
[7] A524 - ICA fines Leadiant 3,5 million euros for abusing its dominant position
[8] Press Release of the CNMC on 14 November 2022: The CNMC fines the pharmaceutical company Leadiant 10.25 million for

New season release: The Commission prohibits the acquisition of Grail by Illumina

The Competition Law community has been impatiently following the outcomes of this intriguing case, introduced in our June 2022 newsletter[9]. As you may recall, it is the first case where the Commission accepted a controversial referral from the French *Autorité de la Concurrence* in a case that did not meet any European or national merger control thresholds.

On the one hand, on 13 July 2022, the General Court upheld the decision of the Commission accepting a referral request from France, as joined by other Member States, asking it to assess the proposed acquisition of Grail by Illumina.[10] The Court ruled that the wording of Article 22 of the Merger Regulation, in particular the use of the expression 'any concentration', makes it clear that a Member State is entitled to refer any transaction to the Commission which satisfies the cumulative conditions set out therein, irrespective of the existence or scope of national merger control rules. It is only this interpretation, says the Court, that ensures the necessary legal certainty and the uniform application of Article 22 of the Merger Regulation in the European Union.

Somehow, this reasoning implies that Article 22 of the Merger Regulation should be understood as a mechanism whose function is precisely correcting imperfections deriving from a strict application of the relevant thresholds. This is clearly the intention of the Commission, now backed by the General Court. What is not so clear is whether this was the intention of the European legislator when adopting the Regulation. This may give rise to a fruitful debate before the Court of Justice, of which we will keep you duly posted.

On the other hand, on 6 September 2022, the European Commission prohibited, under the EU Merger Regulation, the implemented acquisition of GRAIL by Illumina.[11] The merger would have stifled innovation, and reduced choice in the emerging market for blood-based early cancer detection tests.

The Commission decided that if the merger finally took place, Illumina would have had the ability and incentive to engage in exclusionary strategies against GRAIL's rivals. It could, for example, refuse to supply its next generation sequencing (NGS) systems to GRAIL's rivals, raise prices or degrade quality and delay supplies. The Commission considered that these strategies would have had a significant adverse effect on competition in the development and marketing of NGS-based cancer screening tests in the European Economic Area (EEA).

Although uncertainty remains as to the exact outcome of this innovation race and the future shape of the cancer screening test market, protecting the current competition for innovation

[9] Marimon Abogados | Newsletter Healthcare and competition
[10] Judgment of the General Court of 13 July 2022, Case T-227/21, *Illumina, Inc. v European Commission* (appeals pending before the Court of Justice, Cases C-611/22 and C-625/22).
[11] Mergers: Commission prohibits acquisition of GRAIL by Illumina

is crucial to ensure that cancer screening tests with different characteristics and price points reach the market. Whether this interest in protecting competition justifies a prior finding of (future and maybe too uncertain) incentive to foreclose will surely be subject to much debate before European Courts.

Besides, Illumina had proposed some "open-access" remedies in order to address Commission's concerns:

1. A license open to NGS suppliers to some of Illumina's NGS patents, and a commitment to stop patent lawsuits in the US and Europe against the NGS supplier BGI Genomics (China) for three years.
2. A commitment to conclude agreements with GRAIL's rivals under the conditions set out in a standard contract.

The Commission conducted a detailed analysis of the proposed commitments and tested their efficacy with the relevant market participants. However, the Commission concluded that those remedies were not sufficient to prevent the harm to innovation in the field of NGS-based cancer screening resulting from the transaction. It finally prohibited the transaction. The non-confidential version of the decision is not public yet.

This is it for the most relevant part. Alongside these two major decisions (referral and prohibition), other derivatives of the case include the adoption of interim measures against the publicly announced execution of the transaction while merger review was ongoing and the opening of a gun-jumping procedure against both the notifying party and the target (!) We are already awaiting season 3…

European Commission sends a Statement of Objections to Teva over misuse of the patent system and disparagement of rival multiple sclerosis medicine

In close material relationship with the case above, the European Commission is also investigation another case of suspected sham litigation. The EC suspects that the company has engaged in two types of abusive conduct to artificially prolong Copaxone's exclusivity, hindering market entry for competing drugs.

Background

The Commission conducted unannounced inspections at the premises of several Teva subsidiaries in October 2019. On 4 March 2021[12], the Commission initiated proceedings against Teva Pharmaceutical Industries Limited and Teva Pharmaceuticals Europe BV.

Teva is a global pharmaceutical company headquartered in Israel that operates through several subsidiaries in the European Economic Area. Copaxone, Teva's best-selling drug, is

[12] Press Release of the European Commission on 4 March 2021: Antitrust: Commission opens formal investigation into possible anticompetitive conduct of Teva in relation to a blockbuster multiple sclerosis medicine

widely used for the treatment of multiple sclerosis and contains the active ingredient glatiramer acetate, on which Teva held a basic patent until 2015.

Findings

The Commission preliminarily thinks that Teva abused its dominant position in the markets for glatiramer acetate in Belgium, the Czech Republic, Germany, Italy, the Netherlands, Poland and Spain.

The Commission is concerned that Teva has engaged in two types of abusive conduct, with the overall objective of artificially prolonging Copaxone's exclusivity by hindering market entry and acceptance of competing glatiramer acetate-based medicines.

In particular, the Commission preliminarily found that, from February 2015 until present:

1. **Teva may have misused patent procedures** by artificially extending the basic patent protection of glatiramer acetate by filing and withdrawing secondary patent applications, thus forcing its competitors to file increasingly new time-consuming legal challenges.
2. **Teva may have implemented a systematic disparagement campaign** directed at healthcare professionals and has cast doubt on the safety and efficacy of a competing glatiramer acetate drug and its therapeutic equivalence to Copaxone, the statement added.

The case is still at a relatively initial stage. We will have to see if Commission's initial views are confirmed, in which case internal Teva documents found during dawn raids may play a major role, as it is more and more frequent lately.

Disparagement, discrimination or mere criticism… is any of them allowed to dominant companies?

On 6 October 2022, the *Autorité de la Concurrence* (AdC) fined ESSILOR and its parent company, ESSILOR LUXOTTICA, up to 81 067 400 euros for discriminatory business practices between online and in-store sales maintained for more than 11 years.

ESSILOR was considered dominant in the manufacture and wholesale commercialization of optical lenses in France. The AdC found that ESSILOR deployed a strategy to disincentivize online sales, with practices such as limiting the shipment of products, refusal to supply certain online sellers, prohibition to use the brand or logo in online platforms, restricted (or de facto non-existent) guarantees in case of default, etc.

The AcD also considered whether the discourse held by ESSILOR, by which it held that online purchases did not allow the same quality assistance as in-store sales, could qualify as an abuse of disparagement. Although the company's strategy could have generated a lack

of trust in online sales and thereby impacted customers' choices, there was not enough evidence that the denigratory statements were part of a global plan, directed to specific customers and had a concrete impact in online sales in France.

The analysis bears some resemblance with the well-known Avastin/Lucentis saga, which we analyzed in previous newsletters.

Indeed, the AdC has been analyzing in various cases the outstanding features of apparently similar and connected concepts (disparagement, discrimination, criticism) and their possible implications for abuse cases. As a result of this analysis, the AdC has built a legal test to identify an "abuse of disparagement", composed of three stages. This test focuses on the message that is sustained by a company that seems to have a dominant position in the market. Once the message is identified, an analysis of its form and content must be carried out to see whether the message is subjective, unfounded, incomplete or even misleading. If it is, it is then necessary to see the impact actually caused and whether it distorted or somehow interfered in its recipient's freedom of choice.

Disparagement also known as denigration must not be confused with criticism towards another competitor. Disparagement is characterized as a tactic adopted by certain companies to acquire or maintain their dominant position in the relevant market through the disclosure of incomplete, misleading or subjective statements. From the message given, an erroneous image is drawn about the viability and quality of a product or service offered by other companies, leading to their partial or total exclusion from the market. The first effect of this practice is to alter the recipient's ability to choose. This tactic has a direct repercussion on the proper development of competition in the market by altering the veracity of the information available.

The theory seems clear. Practical distinctions between abusive disparagement and admissible criticism may not be so easy…

Other HIGHLIGHTS and FOLLOW-UPs…

Revision of the EU general pharmaceuticals legislation

As advanced in our previous newsletter,[13] a new regulatory proposal is expected soon. We are closely following the discussions among European legislators and will keep you duly posted.

Swiss antitrust investigation against Novartis on use of patents[14] around a drug for skin diseases

On September 13, 2022, the COMCO started an investigation against a Swiss pharmaceutical company and conducted a dawn raid at its premises. The investigation concerns Cosentyx, currently Novartis' best-selling drug, an anti-inflammation drug used for psoriasis treatment.

The investigation aims to determine whether the alleged behavior, consisting of launching litigation against a competitor over a treatment to fight skin disease, constitutes an abusive use of a so-called blocking patent, which might amount to an infringement of the Swiss Cartel Act.

[13] Marimón Abogados | Newsletter Healthcare and competition | June 2022
[14] COMCO : Investigation on use of patents

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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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