MARIMÓN
ABOGADOS

# Pharma & Competition

October 2020

Dear all,

We are happy to start here a series of newsletters dedicated to Competition law issues related to the pharma sector.

As widely held in EU case-law, the pharma industry is not to be treated as an exceptional oasis for Competition law purposes. Antitrust rules fully apply to this industry. However, regulatory specificities and also regulatory differences between Member States do call for some nuances when applying such rules. It is precisely these nuances we are interested in and focusing in with this new series of Newsletters.

This is not a regulatory newsletter. It is a Competition law focused publication treating pharma specificities. It intends to be short, specific and analytical. That's why we will consciously pick and choose some interesting news among all the available plethora of ongoing discussions. We intend to perform this aim to the best of our effort and knowledge and we vigorously encourage you to share any comments that help us improve our new challenging task.

Competition law Team, Marimón Abogados

## The French Competition Authority fines three pharma companies for collective abuse of dominance

On 9 September 2020, the French Competition Authority fined three pharma companies (Novartis, Roche and Genentech) 444 million euros for a collective abuse of dominance (see the press release here). The case is definitely worth a close reading because it raises very interesting issues of Competition law:

**Collective dominance:** this is a well-known but rarely applied concept in Competition law. The authority needs not prove agreements between different companies, nor an individually held dominant position (which requires, in general, very high market shares and market power, with the difficulties associated to market definition). In the case of collective dominance, the authority needs to prove tight links between the undertakings concerned and a sufficient degree of market transparency, which facilitate a collective response to a given market situation irrespective of agreements or contacts between competitors, that are often difficult to prove. Significantly enough, in this case, the French Authority holds that a marketing licence (Novartis holds a licence from Genentech to market Lucentis, an eye disease drug) and capital structures (Roche is Genentech's main shareholder) give rise to collective dominance.

**Abuse consisting of denigrating rivals:** in the context of an eye disease (Age-related macular degeneration, AMD) for which doctors started prescribing a cancer drug (Avastin) that proved useful and was significantly cheaper than Lucentis, Novartis launched a communication campaign denigrating, in an exaggerated and unjustified manner, the use of Avastin without marketing authorisation for the treatment of AMD and for any ophthalmological condition in general, in comparison to the safety attributed to Lucentis. Additionally, according to the French Competition Authority, Novartis, Roche and Genentech spread an alarmist message, sometimes misleading, to public authorities on the risks linked to the use of Avastin for AMD, with the aim of blocking or delaying the initiatives to use it for AMD without market authorisation.


**Relevance for the pharma industry in general:** three factors seem particularly relevant for the decision:

(i) selling a drug outside the scope of its market authorization is generally admitted insofar as doctors prescribe such drug for that different use;

(ii) financed drugs entail a significant expenditure for public authorities; and

(iii) health authorities very much rely on the scientific knowledge and expertise demonstrated and shared by pharma companies. Using such knowledge misleadingly and to the detriment of public finances without legitimate safety/health reasons and for the sole preservation of private economic interests does not amount to competition on the merits and is therefore abusive for Competition law purposes.

This undoubtedly shows the specific sensitivity of the pharma sector, where intended misinformation seems particularly detrimental to the public interest. This seems to us to be building upon, or at least be somehow related to, 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. Interestingly enough, the case below also concerns a similar type of behavior…

## Spanish courts called to rule on whether the complainant ought to be an interested party in MSD's abuse investigation

**Background and substance**

On 21 November 2019, the Spanish Competition Authority (*Comisión Nacional de los Mercados y la Competencia*, CNMC) announced the formal opening of antitrust proceedings against Merck Sharp & Dohme S.A. (MSD) and its European parent company MSD Human Health Holding B.V (see press release). The case is ongoing and concerns an alleged abuse of dominance consisting of misusing judicial action, thereby delaying third-party entry into the Spanish market for combined hormonal contraceptive medicines of the vaginal ring type.

On substantive terms, the case raises again the very interesting issue of sham litigation, very much debated in antitrust doctrine worldwide but scarcely applied due to its undoubted and inextricable link to the exercise of the fundamental right to seek judicial review. Again, the EU ITT Promedia (case T-111/96) and AstraZeneca (cases T-321/05 and C-457/10) are the leading cases thereto. Is a litigant entitled to deception before courts? Where is the limit between a partial interpretation of facts and clear deception? Is a competition authority in a good position to determine the existence of such alleged deception?

In the particular case before the CNMC the main issue consists of determining whether asking for judicial interim relief, *inaudita parte*, on the basis of consciously biased expert evidence may amount to an abuse of a dominant position. The competent judge already ruled on the conscious and deceptive bias (see here). The question is now whether this behaviour may be fined under antitrust rules.

**Procedural dispute**

Whereas the substantive analysis of the case may take several months or even years, highly interesting procedural points have already arisen. On 5 December 2019, MSD filed an administrative appeal against the decision to open proceedings, the main argument being that the CNMC had thereby granted Insud Pharma, S.L., the complainant, access to the file as an interested party and that access may affect MSD's fundamental rights and its right to confidentiality of sensitive information. The CNMC rejected the appeal on 4 March 2020 (see here), and the controversy has now escalated to the National Court of Appeals (*Audiencia Nacional*), probably leading to the temporary stay of the main antitrust proceedings.

Regardless of each parties' respective interests and arguments, the discussion revolves around complainants' status as interested parties in antitrust proceedings. In Spanish Administrative Law, a consolidated line of case-law states that there is no general right for complainants to be treated as interested parties and thereby be granted access to the file and file their observations.

However, the exception that confirms the rule has been admitted repeatedly in Competition law cases. Indeed, case law has also accepted that some complainants may be in a special position *vis-à-vis* the infringer, since they were particularly affected by the alleged anticompetitive practice. What is more, complainants may help the authority construe the case, providing evidence, and they may also give momentum to a paralyzed investigation.

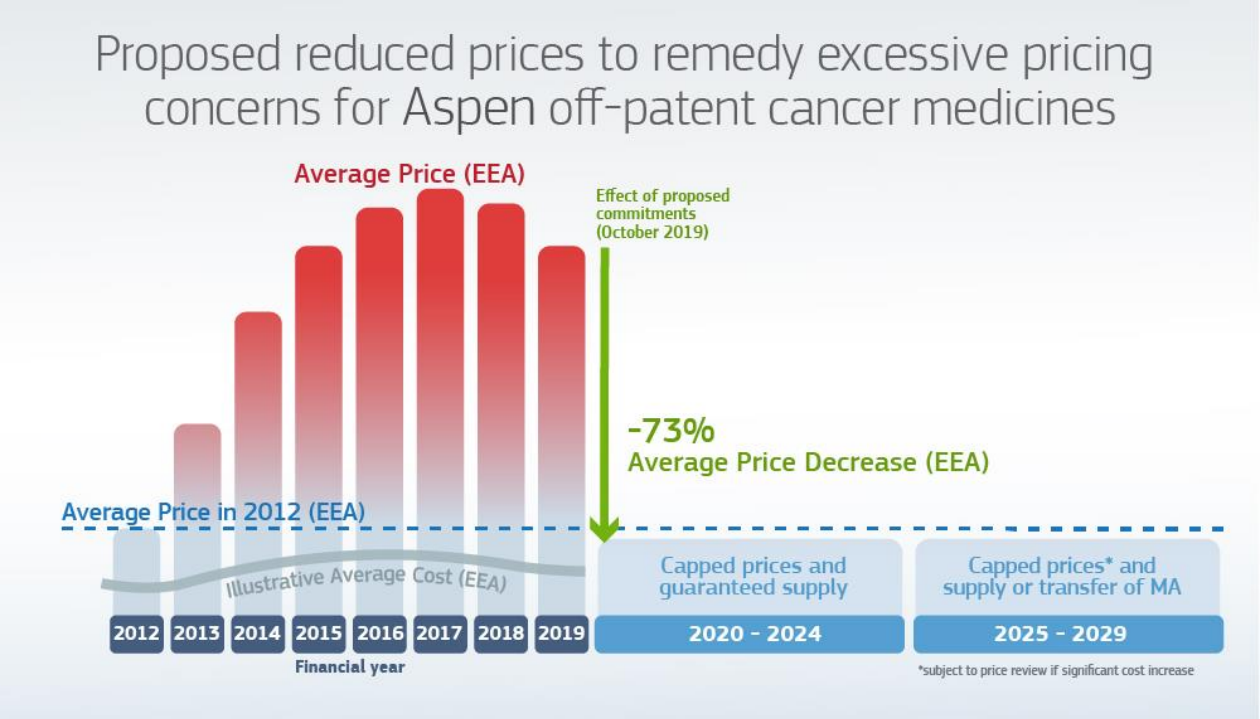
On the other side, the company under investigation has all the incentives to try and avoid such a third-party intervention, other than legitimately fearing access to commercially sensitive information. Such access should of course be avoided, but one may think that statutory provisions already provide the necessary tools to guarantee confidentiality. Should a case be stayed for months or even years on grounds of this prospective -and evitable- access? With expectant interest we shall await judgment on this interesting discussion.

## Commission sought feedback on Aspen commitments to address excessive pricing concerns

On 15 May 2017, the European Commission opened an investigation against Aspen for possible abuse of its dominant position in several national markets, covering the entire European Economic Area, by charging excessive prices for critical off-patent cancer medicines. The case relates to a number of cancer medicines mainly used in the treatment of leukaemia and other haematological cancers, and sold under the brand names Alkeran, Leukeran and Purinethol.

As preliminarily advanced by the Commission, Aspen's prices exceeded its relevant costs by almost three hundred percent on average and the investigation does not reveal any justifications for such high prices. Neither significant investments on innovation, nor any commercial risk taking or unit cost increases seem to justify the behaviour. Aspen could maintain its policy of high prices due to the lack of alternative treatments, thereby adding credibility to its threat to withdraw the relevant medicines from the market.

Aspen's behaviour may be abusive, but a case on excessive prices is not an easy one because it may severely impinge on a company's business freedom -even a dominant company has that freedom! Therefore, the Commission is now considering Aspen's offer of commitments as an alternative means to solve the case. In a nutshell, Aspen proposed:



(i). reducing its prices across Europe for the six cancer medicines by, on average, approximately 73%;

(ii). maintaining such price cuts for ten years and applying them retroactively, as of October 2019; and

(iii). guaranteeing the supply of the medicines for the next five years, and, for an additional five-year period, continuing to supply or making its marketing authorisation available to other suppliers.

The Commission invited any interested party to submit observations on Aspen's proposed commitments before 17 September 2020 (see here). This deadline having elapsed, the ball is again in the Commission's court to assess whether commitments actually address competition concerns identified in 2017.

## Other HIGHLIGHTS and FOLLOW-UPs…

### - The Competition & Markets Authority (UK) and the *Autorità Garante della Concorrenza e del Mercato* (IT) remain very active in the pharma sector

The UK Competition Authority has traditionally been and remains one of the most active competition authorities in the pharma sector. Notably, it currently has an ongoing remittal case on excessive and unfair pricing (see here) and an ongoing investigation on anticompetitive agreements concerning generics (prochlorperazine 3mg buccal tablets) (see here).

The Italian Competition Authority also maintains several abuse investigations ongoing. Excessive prices for ultrarare diseases' treatment are on the radar in the Lediant case (see here) or Altroconsumo's complaint against Biogen (see here).

### - Spanish investigation on radiopharmaceuticals (case S/0644/18) still ongoing

After last year's addition of parent companies to the investigation (see here) there have been no other relevant news. We remain expectant to the final decision.

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**Marimón Abogados** is a law firm founded in 1931 that offers legal services in all areas of law and has offices in Barcelona, Madrid and Seville. Our Firm has adapted to the changes that have taken place in the market by constantly improving its services and expanding its branches of activity, creating specialized departments that have extensive experience accompanying our clients in their daily business activities.

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