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Antitrust developments in the pharma sector – Part II

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This is the second part of a paper that considers recent developments in competition law in Europe relative to the life sciences and pharmaceutical sector. As we explained in Part 1, the sector has continued to be a focus of competition law enforcement in Europe, with the UK's Competition and Markets Authority ("**CMA**"), in particular, pursuing a high number of investigations.[1]

The high level of enforcement activity has in turn given rise to a number of court judgments that have addressed arrangements between actual or potential competitors concerning market sharing and pay-for-delay, as well as exclusionary and exploitative abuse by dominant firms including the denigration of competing products and excessive pricing. Importantly, the judgments have also considered the investigative powers, processes and procedures of the competition authorities and made some important determinations in that regard.

In our first article we considered recent developments under Article 101 of the Treaty on the Functioning of the European Union ("**TFEU**") and Chapter I of the UK competition Act 1998 ("**CA98**"). Here we will consider abuse of dominance under Article 102 TFEU/Chapter I CA98, and in particular excessive pricing and exploitative conduct. We will also consider the competition authorities' general powers, processes and procedures.

ABUSIVE CONDUCT

A. EXCESSIVE PRICING

Introduction

The unilateral setting of high prices is not illegal in itself. However, concerns may arise where the relevant company is dominant. Under Article 102 and Chapter II, unfair pricing by a dominant firm can be an abuse of a dominant position where the prices are at a level that bears no reasonable relation to the "economic value" of the product.

Until relatively recently, the Commission and other European authorities had rarely investigated excessive pricing not least since such cases involve complex issues of law and economics, while competition authorities are reluctant to act as price regulators. In fact, to date, there has been no decision either at an EU or UK level that excessive and unfair pricing is *in and of itself* an abuse of dominance.[2]

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1 This is unlikely to change in the light of the commitment made by the CMA in its Annual Plan for 2021/2022, "*to ensure that the NHS does not pay significantly more than it should for essential medicines and treatments, and that consumers who depend upon these drugs and treatments do not lose out*".

2 To date, authorities have only made a finding of excessive pricing where the market is incontestable and unable to self-correct, for example due to the presence of a statutory monopoly, prior exclusionary conduct

Assessing excessive and unfair pricing following the Court of Appeal's judgment in *Phenytoin*

More recently, the pharmaceutical sector has seen increased enforcement in this area, particularly by the CMA. In December 2016, the CMA issued an infringement decision against Flynn and Pfizer relating to the pricing of phenytoin capsules, imposing record fines totalling £89.4m.

Following an appeal of the CMA's decision, the CAT in *Phenytoin* ("***Phenytoin (CAT)***")[3] set aside the CMA's findings on abuse and the related penalties, heavily criticising the CMA's interpretation of the CJEU's judgment in *United Brands*,[4] and remitted the CMA's decision on abuse to the CMA for further consideration. Following an appeal of the CAT's judgment by the CMA,[5] the Court of Appeal largely upheld the CAT's judgment, dismissing three of the CMA's four grounds of appeal and refused to reinstate the fines ("***Phenytoin (CoA)***").[6]

Following the judgments by the Court of Appeal and the CAT, assessing whether a price charged by a dominant firm is excessive and unfair will take into account the following:

1. The starting point is correctly defining the relevant market, since only if the pharmaceutical firm is dominant can there be an abuse. Although an obvious point, the CMA in Paroxetine sought to establish the patent holder's dominance by reference to the drop in price following generic entry. The CAT in *Paroxetine (2021)* rejected this, since otherwise "*almost every patent holder would be dominant*". The CMA said that the critical question is whether there was a separate relevant market for paroxetine.
2. Establishing dominance in the context of the pharmaceutical sector can be a complex exercise, not least taking into account any countervailing buyer power exercised by the national healthcare service and the applicable regulatory regime.
3. Once dominance is established, the question is whether a price is excessive and unfair. This may be determined by reference to the two-limb analysis described by the CJEU in *United Brands*:
    a. Under Limb 1, establishing if the price charged is "excessive". This can be determined by reference to a "Cost Plus" analysis, namely, the difference between the costs incurred plus a reasonable rate of return;[7] and, *if it is*,
    b. Under Limb 2, establishing if the price is "unfair", either in itself (Alternative 1) *or* when compared to competing products (Alternative 2). In its appeal to the Court of Appeal, the CMA argued there is no obligation to consider *both alternatives*, so if the CMA found that the price was unfair "in itself" then it had no obligation to evaluate whether it was also unfair by comparison to other products. The Court of Appeal rejected this, and clarified that whilst Limb 2 does not confer an obligation on the competition authority to use multiple tests, if a

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or customer lock-in; and/or, where the enforcement focus was on exclusionary conduct and the excessive pricing facilitated the foreclosure or was ancillary to it, for example in the case of cumulative abuses.

3 CAT in *Phenytoin*, 7 June 2018.

4 CJEU in *United Brands*, 14 February 1978.

5 The Commission intervened in support of the CMA's appeal to the Court of Appeal. Flynn Pharma cross-appealed the CAT's judgment, but its cross-appeal was dismissed by the Court of Appeal.

6 Court of Appeal in *Phenytoin*, 10 March 2020. The CMA and the parties did not appeal the Court of Appeal's judgment to the UK's Supreme Court.

7 In the context of the pharmaceutical sector, we consider that "excessiveness" should be established by reference to the firm's portfolio of drugs rather than a single drug, since pharmaceutical firms decide prices on a portfolio basis rather than a per item basis.

party presents evidence under one of the alternatives in Limb 2, then the authority must consider that evidence. Accordingly, the CMA may not rely on a finding that a price is unfair "in itself" and ignore other evidence put forward by a defendant that prices were fair by reference to other competing products.

4. However, whilst a benchmark is required, there is no obligation on the authority to ascertain a hypothetical benchmark price against which to assess whether the actual price charged is excessive. The Court of Appeal said that "*in some cases*" the authority may choose a "Cost Plus" approach to determine if the relevant price is excessive. The Court of Appeal agreed with the CMA that that there is "*no single method or 'way' in which abuse might be established*", and competition authorities have a "*margin of manoeuvre*" in deciding which methodology to use and which evidence to rely upon. However, the authority's "*margin of manoeuvre*" is not absolute and the authority is under an obligation "*to conduct a fair evaluation of all the evidence before it*", which means that, "*If an undertaking relies, in its defence, upon other methods or types of evidence to that relied upon by the competition authority then the authority must fairly evaluate it*".
5. A price will only be excessive and unfair if it bears "*no reasonable relation*" to the "economic value" of a drug. In determining economic value, the authority may not ignore patient benefits, even if the drug involves clinical lock-in.
6. Finally, to date, the pharmaceutical firms found to have charged excessive and unfair prices acted in disregard of the requests by the relevant health authorities. In *Phenytoin (CAT)*, Flynn/Pfizer ignored NHS requests to reconsider their price, with Sir Geoffrey Vos noting that "*literally overnight, Pfizer and Flynn increased their prices for phenytoin sodium capsules by factors of between approximately 7 and 27*"; while in its 2021 commitments decision against Aspen ("***Aspen***"),[8] the Commission factored into its "fairness" assessment the aggressive tactics used by Aspen when applying price increases, including threatening to discontinue supply if its price increases were not accepted, and relying on clinical lock-in to overcome resistance to its prices.

What next?

In the UK, the CMA re-considered its decision in *Phenytoin* following the CAT's remittal and issued a new statement of objections in August 2021. In July 2021, the CMA issued an infringement decision relating to excessive pricing in the supply of **Hydrocortisone** tablets in the UK,[9] as well as an infringement decision relating to excessive pricing in the supply of **Liothyronine** tablets in the UK.[10]

In the EU, the Commission in *Aspen* opted to accept legally binding commitments offered by Aspen to reduce its prices in accordance with Article 9 of Commission Regulation 1/2003, rather than issue an infringement decision. This means that the Commission has not issued a fully-fledged and evidenced infringement decision, and that its decision is unlikely to be subject to an appeal.

Furthermore, even though the CMA in *Phenytoin* and the Commission in *Aspen* applied the *United Brands* two-limb test, both the CAT in *Phenytoin (CAT)* and the Commission in *Aspen* said this is not the only methodology to assess excessive and unfair prices, and noted that the CJEU in *United Brands* clearly left

8 Commission commitments decision in *Aspen*, 10 February 2021.
9 Case 50277 – Hydrocortisone tablets.
10 Case 50395 – Liothyronine.

open the possibility that an abuse of a dominant position through excessive and unfair pricing could be established by other means also.

Both the CMA's decisions in *Liothyronine* and *Hydrocortisone* have been appealed to the CAT, while any decision by the CMA in *Phenytoin* (further to the remittal) may be susceptible to appeal. Since neither the CMA nor Flynn/Pfizer appealed *Phenytoin (CoA)* to the Supreme Court, and it is not expected that Aspen will challenge the Commission's commitments decision, the scope for further legal developments in this highly complex area of law remains.

B. PRODUCT DENIGRATION AND SWITCHING PATIENTS TO MORE EXPENSIVE ALTERNATIVES

In October 2020, the CMA launched an investigation into Essential Pharma suspecting that the company abused its dominant position in relation to lithium-based medicines, which it sells under the brand names Priadel and Camcolit. The CMA said that Essential Pharma adopted a strategy of withdrawing the supply of Priadel from the UK market, which the majority of patients in the UK taking a lithium-based drug rely on, in order to switch patients to Camcolit, a more expensive alternative treatment. The Department of Health asked the CMA to impose "interim measures" to pause the withdrawal of Priadel from the UK market while the investigation was ongoing. Following the opening of the CMA's investigation, Essential Pharma informed the Department of Health that it would pause the withdrawal of the drug.

In December 2020, the CMA announced that it had accepted legally binding commitments from Essential Pharma to continue supplying Priadel at an affordable price for at least 5 years to address the CMA's concerns, as a result of which the CMA closed its investigation.

THE COMPETITION AUTHORITIES' POWERS, PROCESSES AND PROCEDURES

A. A COMPETITION AUTHORITY HAS A DUTY TO CONDUCT A FAIR EVALUATION OF ALL THE EVIDENCE BEFORE IT

The CMA in particular has been actively pursuing pharmaceutical companies for suspected breaches of competition law in areas that had either fallen into disuse (e.g. excessive pricing) and/or in a novel manner, departing from established EU precedent by relying on its so-called "*margin of appreciation*".

In *Phenytoin (CoA)*, Green LJ was keen to note that the CMA is under a duty "*to conduct a fair evaluation of all the evidence before it*", and rejected the CMA's suggestion that the CMA might be justified in not conducting a full investigation of a defendant's evidence because an undertaking can appeal the CMA's decision.

The CAT was also keen to note in *Phenytoin (CAT)* that the CMA's "*margin of appreciation*" does not exclude the presumption of innocence. As the European courts have ruled, "*any*" doubt operates in favour of the undertaking under investigation.

B. FINING

Recently, in *Paroxetine(2021)*, the CAT ruled that the CMA also doesn't have unfettered power in calculating its fine. A specific issue arises in some pay-for-delay and excessive pricing cases given the novel application of the available caselaw by the CMA.

Section 36 CA98 sets out that in order to impose a fine on an undertaking for a breach of competition law, the CMA must show that the company committed the infringement "*intentionally or negligently*". This is

essentially a jurisdictional issue. If the jurisdictional threshold is satisfied, a second, separate but related question arises: whether, given the novelty or complexity of a case, there should be no fine or only a nominal fine.

The CAT in *Paroxetine (2021)* ruled that, on the facts of the case, the CMA had jurisdiction to apply a fine, and went on to consider the CMA's fine calculation under its six-step approach.[11] The question arose whether, given the *novelty* of the case,[12] the CMA's fine calculation in Step 4 was disproportionate. The CMA, exercising its "*margin of appreciation*", said that it had taken into account the novelty of the infringements by deciding not to impose a further uplift at Step 4 to achieve specific deterrence; it also considered that it was appropriate to apply a 10% discount in order to achieve what it considered to be appropriate penalties for each party.

Even though the CAT acknowledged that the CMA has a margin of appreciation when it comes to its determination of a penalty, the CAT nonetheless concluded that the CMA's application of its margin of appreciation in Step 4 of its fine calculation was *flawed*, and ruled that the correct fine reduction in this case, for all appellants, was 40%.

The CAT also ruled that *no* penalty should be imposed on GSK for violation of Article 102/Chapter II, since the approach to market definition on which the CMA had based its finding of dominance was disproved by the CAT in *Paroxetine (2018)*, while, on the facts of the case, the approach to market definition set out by the CJEU in *GSK* was "*somewhat novel*".

[11] The CMA's penalty guidance sets out that the CMA will calculate a financial penalty under section 36 of the CA98 following a six-step approach: first, calculation of the starting point having regard to the seriousness of the infringement and the relevant turnover of the undertaking; second, adjustment for duration; third, adjustment for aggravating or mitigating factors; fourth, adjustment for specific deterrence and proportionality; fifth, adjustment if the maximum penalty of 10% of the worldwide turnover of the undertaking is exceeded and to avoid double jeopardy; sixth, adjustment for leniency, settlement discounts and/or approval of a voluntary redress scheme.

[12] At the time of the impugned settlement agreements, there had been no EU or UK decisions that they could constitute an infringement of Article 101/Chapter I.