Kluwer Competition Law Blog

Liothyronine – The CMA prevails in pharma excessive pricing

Stijn Huijts (Geradin Partners) · Thursday, September 7th, 2023

Many competition authorities would have given up on excessive pricing cases when the Competition Appeal Tribunal (the Tribunal) annulled a fine of more than £80m which the UK Competition and Markets Authority (CMA) had imposed on Pfizer and Flynn for increasing prices for Phenytoin sodium capsules by 700-2,600%. Many, but not the CMA. The UK's competition watchdog instead appealed the Tribunal's *Phenytoin* judgment to the Court of Appeal, adopted two further excessive pricing decisions involving the drugs liothyronine and hydrocortisone, and re-adopted its Phenytoin decision.

That perseverance paid off when on 8 August 2023, the Tribunal upheld the CMA's *Liothyronine* decision, the first public enforcement case focusing only on excessive pricing largely to survive a full merits appeal in the UK (and one of a very short list of such cases in Europe, which includes *CD Pharma* in Denmark and *Aspen* in Italy). The Tribunal's judgment on *Hydrocortisone* is expected soon (it involves an alleged market-sharing agreement alongside the excessive pricing allegations), and the judgment relating to the re-adopted *Phenytoin* decision should follow after that.

This blog post discusses the Tribunal's *Liothyronine* judgment. Between 2007 and 2017, Advanz, the sole provider of liothyronine tablets, raised its prices by a total of 6,000%. Before this, the UK's National Health Service (NHS) spent about £600,000 per year on the drug that has been off-patent for decades. By 2016, this had risen to a whopping £30,000,000 per year despite volumes staying largely the same. The CMA found that this amounted to excessive and unfair pricing in breach of the "*Chapter II prohibition*" (the UK's prohibition on abuse of a dominant position) and imposed fines totalling £101,442,899 on the various entities that formed an undertaking with Advanz, including two private equity firms who successively owned Advanz.

The drug lifecycle

Most synthetic drugs follow a common, relatively long, lifecycle that has three distinct stages. At the risk of oversimplification, these three stages are essentially (i) the pre-launch period when drugs are developed, which is characterised by substantial investment in R&D with no guarantee of commercial success; (ii) the market exclusivity period, i.e., the period from the launch of the drug to expiry of patent protection; and (iii) the post-exclusivity period when, following patent expiry and loss of exclusivity, other pharmaceutical companies can enter the market with generic versions of an originator drug and compete with the originator.

The issue at stake in the CMA's cases is that for some drugs that have come off patent, no meaningful entry occurs because entry is not perceived as being profitable. This is usually because of barriers to entry or because the market is too small to attract entry. It can also be the result of collusion between the originator and potential entrants, a problem seen in the "*pay for delay*" cases in the EU and UK (like *Lundbeck*, *Servier* and *Generics UK (Paroxetine)*).

These generic markets, therefore, do not deliver the benefits of competition. In the industry, these products are known as "*niche generics*". During the relevant infringement periods, pricing for unbranded generic drugs was not regulated in the UK, on the assumption that competition could be relied on to keep prices low. Niche unbranded generics were, therefore, not only shielded from competition but their pricing was also unregulated. By contrast, branded but off-patent drugs were regulated under a scheme called the PPRS. Therefore, in niche generic markets where entry was unlikely, manufacturers who wanted to benefit from unregulated pricing first had to de-brand their product and launch a fully generic version to be free to set their prices.

Little jewellery boxes – How liothyronine tablets became a niche generic

Liothyronine tablets were first sold in the UK in the 1950s. Any patents relevant to the sale of the product in the UK expired no later than the 70s. The product continued to be sold under its brand name Tertroxin, and Advanz acquired it in 1992. Until Advanz de-branded the drug, the price under the PPRS remained low: in September 2007, the average selling price (ASP) was the equivalent of £4.05.

In October of the same year, Advanz de-branded the drug and introduced an unbranded generic version. From this point onwards, liothyronine tablets sold by Advanz became a generic drug outside effective price regulation. Advanz made use of its freedom to set prices by steadily increasing the price of liothyronine tablets from £4.05 (for a pack of 28) to a peak level of £247.87 in July 2017, representing a price increase of 6,021%.

Some of the steepest price increases occurred when Advanz was owned by private equity firm Cinven. As the judgment highlights, when acquiring Advanz, a Cinven partner explained to the Financial Times how the company was planning to use cheap off-patent medicines with limited risk of price competition to attract strong sales, referring to them as "*little jewellery boxes*", and naming liothyronine tablets as one such drug.

Only after prices had risen by more than 6,000% did entry by competitors finally occur, in August 2017. Therefore, between October 2007 and August 2017, liothyronine tablets faced no competition and no pricing regulation.

Phenytoin's long shadow

To understand the approach taken by the CMA and subsequently the Tribunal in *Liothyronine*, it is important to pause briefly on the state of play after the two judgments in *Phenytoin*, the first in this series of CMA excessive pricing cases.

The *Phenytoin* case also features a niche generic, phenytoin sodium capsules. In December 2016,

the CMA found that Pfizer and its distributor Flynn had engaged in excessive and unfair pricing for this medicine by de-branding the product and subsequently increasing prices by up to 700-2,600%. The companies both appealed the decision to the Tribunal, which set the CMA's decision aside on the issue of abuse.

Although the Tribunal and the Court of Appeal agreed that the CMA was right to use the test from the CJEU's *United Brands* judgment with respect to prices for phenytoin sodium tablets, it did not agree with the way in which the CMA had applied the test. Under that test, a price is abusively high if a cumulative twolimb test is met: (i) the difference between the costs actually incurred and the price actually charged is excessive (the "*Excessive Limb*"), and (ii) a price has been imposed which is either unfair in itself or when compared to competing products (the "*Unfair Limb*").

Under the Excessive Limb, the CMA had first compared prices to Pfizer and Flynn's costs allocated to manufacturing the product, plus a reasonable return (known as "*Cost Plus*") and had concluded that prices were indeed excessive. The Tribunal, however, held that to calculate the excess in accordance with the Excessive Limb the CMA needed to compare the prices charged to a benchmark price or a range of prices (that represented workable competition), and could not rely only on a comparison with a Cost Plus calculation.

The CMA had then assessed a number of factors to determine whether the economic value of phenytoin sodium capsules was higher than Cost Plus and had concluded that it was not: there were no "*non-cost related factors*" that would lead to a higher economic value. Taking into account various other factors, the CMA had concluded that prices were not only excessive, but unfair in themselves. The Tribunal held that the Unfair Limb did not consist of two strict alternatives (unfair in itself or unfair when compared to competing products) but that whichever alternative the CMA chose to use, it would always need to give due consideration to any "*prima facie convincing argument*" that the price was actually fair under the other alternative, suggesting in one part of the judgment that the CMA should carry out a "*full investigation*" into such claims. Ultimately, the Tribunal proposed a new eight-step test that a competition authority would need to follow to meet the *United Brands* test. The Tribunal remitted the case back to the CMA.

The CMA appealed that judgment to the Court of Appeal, which upheld the Tribunal's decision to remit the case back to the CMA. However, the Court of Appeal did not agree with the Tribunal on everything and clarified the test that the CMA would need to apply, bringing to an early end the Tribunal's nascent eight-step test for excessive pricing. In particular, the Court confirmed that it was not necessary for the CMA to compare prices to a hypothetical benchmark price to meet the Excessive Limb. In the appropriate case, a correctly calculated Cost Plus can function as a robust benchmark against which prices could be compared. Under the Unfair Limb, the Court agreed that the CMA could reach a conclusion under one of the two alternatives but would have to evaluate other prima facie evidence that prices were fair adduced by a defendant undertaking. This did not, however, need to involve a "*full investigation*", and the lengths to which the CMA would need to go would depend on the strength of the evidence adduced by the company under investigation.

Enter liothyronine tablets

The CMA adopted its decision on *Liothyronine* on 29 July 2021. The decision was addressed to Advanz, the pharma company that supplied liothyronine tablets, as well as the two private equity

firms Hg Capital and Cinven that respectively owned the majority of the shares in Advanz at different times during the infringement period.

In its decision, the CMA found that Advanz held a dominant position and that its prices were excessive and unfair under the *United Brands* test, as clarified by the Court of Appeal in *Phenytoin*. In particular, the CMA assessed Advanz's direct costs, indirect costs and a reasonable rate of return (together forming Cost Plus) and showed that the differential between Advanz's prices and its Cost Plus ranged between 900% and 2,500%. The CMA applied a series of sensitivities (i.e., alternative approaches) to the data used in its Cost Plus analysis, intended to function as cross-checks to the Cost Plus analysis. The CMA concluded that Advanz's prices were excessive.

There were no demand-side factors that would add (or materially add) to the economic value of Advanz's Liothyronine Tablets. The price was unrelated to its therapeutic value. There was no evidence that the NHS was ready and willing to pay a premium for liothyronine tablets. The CMA concluded that prices were unfair in themselves, having regard to a number of factors including the substantial disparity between price and economic value, the significant impact of Advanz's conduct on the NHS, and others.

The Tribunal's judgment

All three addressees appealed the decision. The main factual issue distinguishing *Liothyronine* from *Phenytoin* is that after the period of infringement with respect to liothyronine tablets ended, two generic pharmaceutical companies had entered the market, leading to a drop in prices and in Advanz's market share. In their responses to the CMA's case, as well as their appeals, the parties based various arguments on this factual situation which merit discussion.

For example, the parties argued the CMA had ignored the basic test for unfair pricing, as set out in *United Brands* and *Phenytoin*, which required a demonstration that "*the dominant undertaking has reaped trading benefits which it could not have obtained in conditions of normal and sufficiently effective competition, i.e., workable competition*". In other words, they argued that the CMA should take the prices that would result from workable competition as its benchmark to assess the fairness of Advanz's real-world prices. However, citing Lord Justice Green in *Phenytoin*, the Tribunal held that there is no rule that the competition authority must establish workably competitive prices at any stage. That being said, it would also be wrong over-rigidly or exclusively to rely on a Cost Plus analysis at the expense of a proper consideration of competition. Ultimately, it is necessary to have regard to the particular circumstances of the product in question, as the Court of Appeal had already held in *Attheraces*.

With respect to the way the CMA had analysed Advanz's prices, the parties argued that the CMA had erred in its assessment of (i) Cost Plus; and (ii) the comparators the parties had put forward.

The Tribunal's treatment of the parties' arguments relating to Cost Plus is highly case-specific and is covered well elsewhere. Suffice it to say that the Tribunal concluded that, "*notwithstanding the Appellants' many challenges, there were no material errors in the CMA's Cost Plus calculation*". The key takeaway is that from a relatively little-used concept in competition law, Cost Plus is becoming the key benchmark for exploitative cases. Provided cost allocation and determination of a reasonable return on investment can be done robustly with the available data, Cost Plus is the

cornerstone of the Excessive Limb.

That said, one aspect of the judgment merits discussion here: the Tribunal's dismissal of multi-firm Cost Plus. The parties submitted that, in a competitive market with multiple suppliers, each firm would need to recover its costs over a smaller share of the market so that unit costs would be higher than in a market with a single supplier. As a result, the CMA should have adjusted its Cost Plus analysis to account for this. Doing so would have a material impact on the Cost Plus figure, which would be about twice as high on the basis of a three-firm Cost Plus, and about three times as high on the basis of a five-firm Cost Plus. The Tribunal, however, disagreed and found that a multi-firm Cost Plus is not an appropriate tool for assessing the fairness of a dominant undertaking's prices, mainly because the proposed adjustment would be unrelated to the incumbent's actual costs incurred in a single-party market, allowing it to retain "*as pure profit*" the costs of operating in a hypothetical multi-player market.

The comparators don't compute

The novel aspects of the judgment are not to be found in its treatment of Cost Plus but in that of the comparators put forward by the parties but dismissed by the CMA, in particular post-entry prices and entry-incentivising prices. The Tribunal accepted almost entirely the CMA line that these potential comparators were "*contaminated*" by the abusively high prices that Advanz had charged.

Post-entry prices

Post-entry prices are the average selling prices charged in a market characterised by excessive pricing after those high prices have attracted entry. The CMA and the parties did not disagree on the potential validity of post-entry prices as a comparator. Their disagreement related to whether the prices seen after entry in this case reflected the outcome of "*workable*" competition.

The parties' experts submitted that the price charged in February 2021 (which remains redacted) was a competitive price. They argued that there was no dominant position or evidence of collusion post-entry, and prices and market shares had dropped substantially. Market shares also fluctuated significantly, suggesting significant switching. ASPs had declined by 34% within one year from entry and 56% within two years compared to the peak price of £248. There had been improvement in non-price competition, with the introduction of new dosages, a longer shelf-life tablet, a lactose-free tablet and a capsule (as opposed to a tablet). The market was therefore "*workably competitive*". Whether post-entry prices were sticky or contaminated, as the CMA had found, was a "*pointless distraction*". Whether the market was workably competitive depended on the structural features of the market. If that analysis shows workable competition, the prices that emerge from it must, by law, be regarded as valid comparators for the purposes of assessing the fairness of prices.

The Tribunal, however, dismissed these arguments on the basis of four factors. First, the price of liothyronine tablets at the time of entry was exceptionally high. Second, prices declined unusually slowly post-entry when compared to other generic markets, indicating that the price in February 2021 was not sufficiently competitive to be a reliable comparator. Third, the Tribunal was satisfied that the price of liothyronine tablets in February 2021 was a substantial outlier by comparison to other generic drugs, including other drugs covered in a report by Oxera, overseas liothyronine

tablets, and levothyroxine tablets. No adequate explanation was given for liothyronine tablets' outlying status in these comparisons. Fourth, the analysis by the CMA's expert, which went undisputed, showed that Advanz and the two entrants were still likely to be earning profits significantly above the profitability expected for a drug developed in the 1950s.

The essential point is this. Post-entry prices can be a relevant benchmark if they represent the outcome of normal and effective competition. Entry that successfully and swiftly brings prices down may be effective, but the resulting prices may not yet reflect the result of normal competition so long as they are on a downward trajectory from the excessive prices previously charged by a single supplier who dominated the market. Here, there were two key issues: competition commenced when prices were at a very high level, and prices declined unusually slowly post-entry. The result of these two factors was that regardless of the fact that February 2021 was 3.5 years post-entry, the benchmark price suggested by the parties was an outlier when compared to other generic drugs, leading to much higher margins than would be expected for such an old drug. Anyone seeking to rely on post-entry prices as a benchmark therefore faces the task of demonstrating that these prices represent the outcome of normal and effective competition, rather than simply a dot on the map towards it.

Entry-incentivising prices

Entry-incentivising prices are the prices that incentivised entry attempts by other suppliers of liothyronine tablets. According to the two private equity firms in their appeals, the CMA's Cost Plus model would result in dominant undertakings being required to price at a level that would foreclose entry. A price of £45.52 per pack of liothyronine tablets was the entry-incentivising price because that was the level when Morningside (one of the two later entrants) began its entry efforts. However, there was some disagreement on whether Morningside was the relevant party in this respect, or whether this was, in fact, a company named Uni Pharma, which considered entering in 2010 when the price was only £21.

The parties put forward a variety of arguments in support of using entry-incentivising prices as a comparator, which all relied in some way or other on the importance of fostering competition. They argued, for example, that it did not make sense to set a benchmark at a level that precluded entry when the benchmark was intended to estimate a price under conditions of workable competition. Similarly, it could not be the case that a dominant firm should be prevented from pricing at a level that would attract entry. Indeed, its "*special responsibility*" was not to restrict competition. Cinven even went as far as to say that the CMA's intervention, in this case, was *ultra vires*, as the CMA was required by law to promote competition, whereas its approach would set a cap on prices in this market that would have deterred competition. The parties also disagreed with the CMA's view that barriers to entry were high in this market.

The CMA's expert, Professor Tommaso Valletti (former Chief Economist at DG Comp), argued that it would be perverse to use entry-incentivising prices as a benchmark for a competitive price because, however high the entry-incentivising price, the logic of the parties' argument was that such a price could not be excessive because any lower price was insufficient to trigger competition. The argument, if accepted, would rule out the existence of excessive pricing abuse.

The Tribunal held that the CMA was right to dismiss entry-incentivising prices as a relevant

competitive benchmark. Citing the Court of Appeal in *London & South Eastern Railway Ltd and others v Gutmann*, the Tribunal noted that "*the law relating to abuse of dominance is concerned with the protection of consumers from the unfairness which arises when a dominant undertaking is freed from competitive shackles*". Instead of protecting consumers from unfairness, treating entry-incentivising prices as a benchmark would allow the dominant undertaking to benefit from high barriers to entry. The use of entry-incentivising prices would also run counter to *United Brands*, as it may lead to prices being charged that show no reasonable relationship to the economic value of the product.

In addition, entry-incentivising prices also rely on the subjective intentions of third parties and are therefore inherently unreliable, making them unsuitable as a proxy for a workably competitive price or as the dividing line between a fair and unfair price. Indeed, their unreliability was illustrated by the wide range between the prices that incentivised Uni Pharma, Morningside and Teva to consider entry in this case. The Tribunal also disagreed with the view that the CMA's approach would disincentivise entry and thus deprive consumers of the benefits of competition. There is nothing in the *United Brands* test that confirms that a benchmark must be set at a level that facilitates competition. It is also not required under that test to compare the harm from high prices to the benefits of competition. Even if such a requirement did exist, the incremental benefits to consumers (availability of different dosages, a longer shelf life, a lactose-free option and increased security of supply) were disproportionately small compared to the increase in prices needed to stimulate entry.

Key takeaways and what comes next

For me, the key point to take away from this judgment is that by working through the appeal stages in *Phenytoin*, the CMA has clearly come to a place where the legal framework for excessive pricing cases is settled as a workable and meaningful test. It consists of two distinct stages, the Excessive Limb and the Unfair Limb. This judgment confirms that the Excessive Limb will often involve a comparison of prices to Cost Plus, but that will not be the end, as an over-rigid reliance on Cost Plus at the expense of a proper consideration of competition is wrong. The agency that builds an excessive pricing case must therefore apply sensitivities as "*cross-checks*" on its Cost Plus analysis and where necessary make the appropriate adjustments.

This judgment also confirms that under the Unfair Limb, the burden of proof can be discharged by relying on "*unfair in itself*", while providing reasoned dismissals of the comparators put forward by the defendant. The interesting thing about the comparators put forward by the appellants in this case was that they relied (in part) on prices charged after competitors had entered the market. In my view, the CMA and the Tribunal were correct to dismiss those prices in the specific circumstances of this case. It would be wrong to use a price charged *after* the infringement period simply because it is a price that in some way reflects the competitive process that kicked off after entry occurred. To be useful as a benchmark, the price must reflect the outcome of normal and effective competition. This is not the case where the price is still on a downward trajectory following entry or continues to be contaminated by the abuse for other reasons.

This judgment presents an opportunity for the Department of Health and the Scottish and Welsh health authorities to claim damages on a follow-on basis. Indeed, it is clear that there are damages from the conduct and that there would be a causal link between damages and infringement. The

open question is what the counterfactual of the abuse would be, and whether it would require the claimants to establish the dividing line between a fair and an unfair price. However, the Tribunal is known to wield a "*broad axe*" when dealing with such issues, and it may be able to sidestep an exercise that would seem to amount to spurious accuracy.

A final point relates to self-assessment. The *United Brands* test is useful to establish abuse but provides little *ex ante* help when dominant firms are setting their prices. This is because there is no requirement to price at Cost Plus, it is only problematic to charge prices that are significantly and persistently *in excess of* Cost Plus. That leaves open the question of where the line can be drawn above which an abuse is committed. There is no clear bright line that can be identified on the basis of the case law as it currently stands.

But perhaps this is exactly right. Excessive pricing cannot be compared to setting a speed limit. Successful excessive and unfair pricing cases represent excesses, which are by nature exceptional. It would not be right for competition authorities or the courts to prescribe an *ex ante* tool to determine what amounts to a "*fair price*", as this would in effect amount to price regulation of large parts of the economy. The upshot is that dominant companies who benefit from pricing freedom bear the responsibility of not abusing that freedom in a manner that is exploitative.

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The author has previously worked at the CMA, including on the CMA's pharma cases, though he was not closely involved in the Liothyronine case. No further disclosure is warranted in his current position.

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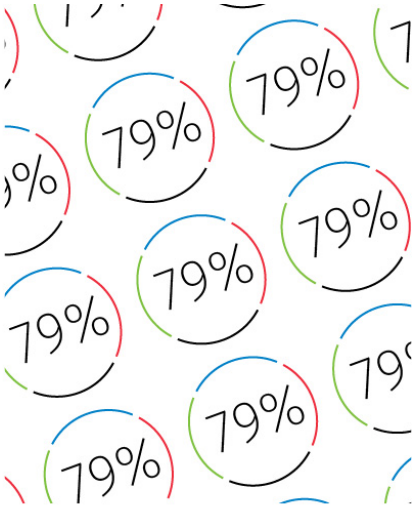

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