Drug Rulings Clarify Pricing Test And Penalty Reviews

By **Andrew Morrison, Deirdre Carroll and Jindrich Kloub** (August 28, 2026)

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This summer has marked a watershed for two of the longest-running sagas in U.K. competition law. On June 19, the Court of Appeal handed down judgment in Pfizer Inc. and another v. Competition and Markets Authority (also referred to as Phenytoin II).[1] And on July 28, it handed down judgment in Auden Mckenzie and another v. CMA (also referred to as Hydrocortisone II).[2]

Together, the decisions do two things.

First, they settle the legal test for excessive pricing in the U.K., giving public and private enforcement a clear body of Court of Appeal precedent to build on.

Second, they hand the CMA significant wins on liability, while leaving the fines in both cases unresolved.

The Court of Appeal firmly restated that companies' rights within Article 6 of the European Convention on Human Rights require the Competition Appeal Tribunal, or CAT, to consider penalty challenges in full and to give reasoned decisions for its conclusions.

This article discusses two key areas of these decisions: the increasingly well-settled test for excessive and unfair pricing, and the scope of judicial review of CMA fines and related strategic considerations.

Context

Both cases concern the evolution of prices of so-called end-of-life medicines, which often end up being supplied solely by originators at prices close to cost. In each case, the products were acquired by third parties who removed them from the relevant pricing regime for branded medicines and proceeded to increase prices significantly.

Such price increases were possible due to unique clinical and/or regulatory barriers that restricted the ability of third parties to enter the market while the products remained clinically essential. These cases cut to the heart of the question as to what is a reasonable price to pay to maintain the supply of low-volume, old, but lifesaving essential medicines.

This is a polarizing question that touches on the need to ensure that these types of medicines can be made available to patients while remaining economically viable.

Phenytoin Appeal

The CMA conducted a lengthy investigation of Pfizer and Flynn in relation to the supply of Phenytoin capsules in 2016, and fined both companies. Following a successful appeal by Pfizer and Flynn, the CAT concluded that the CMA had failed to adequately consider comparator products and remitted the matter to the CMA for reevaluation.

In 2022, the CMA issued a fresh decision, again finding an infringement on similar terms and fining Pfizer and Flynn. On appeal, the CAT set aside that decision and substituted its own decision to find an infringement.

Both the companies and the CMA appealed the CAT decision to the Court of Appeal.[3] The CMA argued that the CAT was wrong to set aside the CMA's decision. Conversely, the companies argued that the CAT, while correct to overturn the CMA's decision, erred in substituting its own reasoning to uphold the CMA's fines.

The appeals covered a range of grounds including the CAT's legal framework for assessing excessive pricing, assessment of comparators and a number of procedural grounds in relation to the CAT's findings.

The Court of Appeal allowed all the appeals, setting aside the CAT's judgment. Notwithstanding that the Court of Appeal held that the CAT was wrong to set aside the CMA's decision, it did not automatically reinstate the CMA's decision, and instead has requested submissions from the parties on the point and any consequential issues as to penalties.

Hydrocortisone Appeal

The CMA's decision in 2021 found that not only that the Auden Mckenzie Group, Accord-U.K. Ltd. (formerly Actavis U.K. Ltd.) and Intas Pharmaceuticals were responsible for an abuse of dominance, but also that Auden and subsequently Actavis/Accord had engaged in so-called pay-for-delay agreements in breach of Chapter I in the Competition Act 1998 prohibition.

In 2023, the CAT upheld the CMA's abuse of dominance findings, but set aside the CMA's Chapter I findings on procedural grounds. The CMA sought and obtained an expedited appeal on the CAT's findings on the Chapter I infringement, with the Court of Appeal reinstating the CMA's decision on the Chapter I infringement.[4]

Each of the businesses subject to the excessive pricing decision appealed the CAT's decision on both liability and penalty, a matter that was eventually heard in March 2026.

The appeals covered a broad range of grounds, including the CAT's legal framework for assessing excessive pricing, assessment of comparators, dominance, attribution of liability, and both the CMA's approach to penalty and the CAT's lack of substantive assessment of those grounds.

The Court of Appeal dismissed the companies' appeals as they related to liability, but upheld their appeals on penalty, remitting the matter to the CAT.

Analysis

Two aspects of these decisions merit closer attention: how the Court of Appeal has settled the legal test for excessive pricing, and how it has restated the CAT's obligations when reviewing penalties. We consider each in turn.

Excessive Pricing

Both judgments confirm that the governing legal test is the simplified two-limb approach devised by the CAT in 2024 in Le Patourel v. BT Group PLC.[5] The first limb is an

accountancy-led exercise to establish whether prices are excessive by reference to the cost of production plus a reasonable rate of return — known as cost-plus. And the second limb is a holistic evaluation of whether that margin is unfair.

The Court of Appeal has endorsed this approach on three occasions: refusing permission to appeal in Le Patourel,[6] Phenytoin II and Hydrocortisone II, making it the settled framework for assessing excessive pricing cases.

In the present cases, the CAT assessed excessive pricing through a novel framework that it devised in its Hydrocortisone decision and predated Le Patourel, which considered three scenarios in which prices might exceed cost-plus:

- Case 1 scenarios where prices are in excess of cost-plus due to relative inefficiencies of competitors;
- Case 2 scenarios, where prices are in excess of cost-plus due to inherent product benefits; or
- Case 3 scenarios, where prices are in excess of cost-plus due to market power and not product characteristics.

In each case, the CAT concluded that the companies' pricing practices were in the third category and were presumptively unlawful. The parties appealed, arguing that such a categorization both ignored preexisting case law that did not provide for any such presumption, and unlawfully reversed the burden of proof.

The Court of Appeal dismissed the arguments that the CAT's use of this framework either failed to take into account the Court of Appeal's previous case law or reversed the burden of proof. Instead, it concluded:

- In Hydrocortisone II, the CAT's three-case taxonomy generated complexity and uncertainty that was undesirable in applying the test set out in Le Patourel, and accordingly, "the three-case taxonomy is not something which should be used as a framework for analysis in the future."[7]
- Notwithstanding this, the CAT had applied the Le Patourel test correctly, addressing in substance all factors relevant to fairness.
- The CAT's approach had not shifted the burden of proof to the appellants, and only placed an appropriate evidential burden on the appellants to explain their prices.

The second key consideration of the Court of Appeal in both Phenytoin II and Hydrocortisone II is the assessment of comparators. In each case, the companies had relied on alternative forms of the same active pharmaceutical ingredient that were available to justify the prices charged. Conversely, in each case, the CMA and subsequently the CAT dismissed such comparators in favor of an assessment of prices years after the start of the infringements.

The Court of Appeal found no legal error in the CAT's approach, and held that there was not an evidential burden on companies to justify the use of comparators. The CMA could use

future price evolution as evidence of the fair price.

The reasoning relied upon by the CMA in each case to place no weight on the comparators identified by the companies was the assertion that there was no evidence to suggest those prices were competitive. This poses serious challenges for businesses in assessing whether prices above cost-plus will be legal.

Penalty Assessment

The Court of Appeal in Hydrocortisone II makes clear that parties are entitled to have the CAT and the Court of Appeal fairly consider the fines levied against them by the CMA.

The companies argued that the CAT's consideration of the CMA's fines was unlawful because the CAT dismissed the parties' lengthy submissions in full in two paragraphs on the basis that it had identified no material error in the CMA's calculations.

The Court of Appeal confirmed the position established in Napp v. DGFT in 2002 that it has full jurisdiction of appeals in relation to the penalties imposed by the CMA,[8] which can only properly be exercised if the CAT provides adequate reasons for its decision.[9]

This highlights two important matters of law. First, it is a reminder that although the Court of Appeal is only entitled to consider points of law when considering appeals on liability, an appeal on penalty is not subject to such limitations.

Second, in reaffirming the findings in Napp, the Court of Appeal has placed an obligation on the CAT to provide adequate reasons to explain its findings.

The Court of Appeal is clear that this does not prevent the CAT from adopting the CMA's reasoning, but it must positively assert why it is doing so by reference to the parties' arguments.

Accordingly, the Court of Appeal remitted the matter of penalty to the CAT for further consideration. It recognized that certain points, as follows, should be considered on remittal:

- As per its decision in Ping Europe Ltd. v. Competition and Markets Authority in 2020, that the requisite intention is satisfied where the undertaking is aware of the facts giving rise to the infringement; intention to commit an antitrust infringement is not required;[10]

- The appropriateness of adopting a blanket approach across all entities within an undertaking when assessing the severity of each entity's infringement uplifts, such as for director involvement, specific deterrence and proportionality; and

- The totality of sanctions imposed on a party across all related infringements.

Takeaways for Businesses

First, while greater clarity over the correct legal test is welcome, the Court of Appeal's endorsement of liability findings based on comparator prices not available to the parties at the time of the relevant pricing decisions adds to the challenges businesses now face when setting prices, both in the pharmaceutical sector and beyond.

When setting prices, not only must businesses now be mindful of an unknowable future cost-plus benchmarking exercise, based on an unknowable economic assessment by a regulator or court, but also their ability to price by reference to similarly priced products has been significantly compromised.

In practice, businesses that may be considered to hold a dominant position need to be particularly vigilant. When setting prices, businesses should take into account and document, where relevant, their assessment of the objective factors informing pricing decisions, including:

- Direct costs of production of the products;
- How a proposed price increase compares to the historic prices;
- Relevant price benchmarks and justifications;
- Input cost increases — either product-specific costs or central fixed costs;
- The importance of any portfoliowide pricing strategy; and
- Specific improvements to the product or other factors with specific value to the purchaser that justify price increases.

Second, an appeal should not focus on liability to the exclusion of penalty. While a win on liability removes all financial sanctions, the CAT's findings are only capable of being appealed on points of law. With a more extensive onward right of appeal, a strong appeal on penalty is a potent tool for businesses to reduce financial liability for infringements of U.K. competition law.

Conclusion

The Court of Appeal's decisions in Phenytoin II and Hydrocortisone II mark the likely conclusion of the arguments on liability, and with them an increasingly settled legal position for assessing excessive pricing. Nevertheless, the application of the fairness test remains complicated and will turn on the facts and evidence in individual cases.

Potentially dominant businesses should ensure that pricing decisions are taken by reference to clear, documented evidence, taking into account a broad range of objective factors.

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[1] Pfizer Inc. and another v. CMA [2026] EWCA Civ 765 (Phenytoin II): https://assets.publishing.service.gov.uk/media/6a352d500bea238415c9a30c/final_judgment.pdf.

[2] Auden Mckenzie and another v. CMA [2026] EWCA Civ 974 (Hydrocortisone II): https://assets.publishing.service.gov.uk/media/6a6883a13c7198e7d0a4c187/Court_of_Appeal_judgment.pdf.

[3] Pfizer Inc. and ors v. CMA [2024] CAT 65.

[4] Allergan Plc v. CMA [2024] EWCA Civ 1023.

[5] Le Patourel v. BT Group PLC [2024] CAT 76.

[6] [2025] EWCA Civ 1061.

[7] Hydrocortisone II, at para. 86.

[8] Napp v. DGFT [2002] CAT 1.

[9] Hydrocortisone II, at para. 223.

[10] Ping Europe Ltd. v. Competition and Markets Authority [2020] EWCA Civ 13.