The first interim relief application under new CAT Rules:

Flynn Pharma Limited v Competition and Markets Authority [2017] CAT 1 (19 January 2017)

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Introduction

By its Decision of 7 December 2016 the Competition and Markets Authority ("CMA") found that Flynn Pharma's prices (and those of its supplier Pfizer) for phenytoin sodium capsules in the UK were excessive and therefore an abuse of a dominant position contrary to section 18 of the Competition Act 1998 ("CA98"). Phenytoin is an off-patent drug used to treat epilepsy. Phenytoin capsules were marketed by Pfizer under the brand name Epanutin until 2012. In 2012 Pfizer transferred its marketing authorisations to Flynn as part of new arrangements for the distribution of the drug. Flynn then 'de-branded' the product the effect of which was to remove it from price regulation under the Pharmaceutical Price Regulation Scheme ("PPRS"). Once outside the PPRS the cost of the drug to the NHS increased eye-catchingly from approximately £2 million in 2012 to £50 million in 2013, £42 million in 2014 and £37 million in 2015, a period during which the number of users was declining. The Decision contained directions that that Flynn (and Pfizer) should reduce their prices of Phenytoin capsules with effect from 23 January 2017.

Flynn and Pfizer have both indicated they intend to appeal against the CMA's Decision. Flynn however brought an urgent application for interim relief under Rule 24 of the Competition Appeal Tribunal Rules to prevent the Directions from taking effect until its appeal had been resolved. Flynn argued that the Directions would cause it serious and irreparable harm including financial losses, a potentially permanent effect on market prices and changes to the organisation of its business. Flynn offered a cross-undertaking in damages intended to protect the NHS against financial losses which interim relief would cause. The CMA opposed the application and the Department of Health intervened in support of the CMA.

The legal test for interim relief in the CAT: a different approach?

The Competition Appeal Tribunal ("CAT") noted that the purpose of interim relief in the CAT is to preserve the integrity of an appeal pending its determination. Rule 24 came into force on 1 October 2015. It replaced Rule 32 of the 2003 Rules. In particular, Rule 32 had made express reference to purpose of "preventing serious and irreparable damage to a particular person or category of person" or the "public interest". In Rule 24 however the reference to "serious and irreparable damage" in rule 32 has been replaced by the concept of "significant damage". Further, unlike Rule 32, Rule 24 makes reference to the "existence and adequacy of any offer of an undertaking as to damages."

The CAT concluded that *American Cyanamid* principles applicable in the civil courts in the context of the grant of interim injunctions are not determinative of the issues which arise under Rule 24 of the Rules because such an appeal does not involve 'party and party litigation' and the CMA is not required to offer any cross-undertaking in damages. Accordingly the CAT considered that its approach in its previous caselaw, notably *Genzyme*, should be modified.[1]

The change in wording in Rule 24 is certainly of note, although it is worth asking if the CAT's explanation for the change is correct what is the problem this amendment was considered necessary to address? The *American Cyanamid* principles are flexible enough to apply in cases where more than the interest of the parties to the dispute is at stake. Examples include intellectual property cases (of which *American Cyanamid* itself was one) and public procurement cases.[2] Indeed even in 'party party' cases the public interest in competition not being restricted when an interim injunction or interdict is sought in the civil courts of the UK is still a valid and permissible consideration. The answer therefore appears to lie elsewhere. One difference is that given that it is generally unlikely to be appropriate for the CMA to give an undertaking in damages the mere causing of some irrecoverable financial loss from a CMA direction may be insufficient to obtain interim relief. There is also in this context no automatic suspension of a direction as a result of an appeal, unlike the position in relation to a penalty. The CAT appeared to reject the suggestion that the public law context meant there was any "strong presumption" against the grant of interim relief under Rule 24.

Advisers will certainly be considering whether the new test of harm in Rule 24 could provide a different outcome in certain situations to that under Rule 32. Both the CMA and Flynn argued their respective cases on the basis that the relevant harm was both 'substantial and irreparable'. (emphasis added)

[1] Genzyme v OFT [2003] 8.
[2] See e.g. Smith v ILEA [1978] 1 All ER 411 (CA); Excel Europe v University Hospitals Coventry & Warwickshire NHS Trust [2010] EWHC 3332 (TCC) (21 December 2010)

The CAT also mentioned the closest analogous situation was the grant by the European Court of Justice of interim relief against a decision of the European Commission.

Application of the test in Flynn's case

The CAT accepted that Flynn had an arguable case. It also accepted Flynn's submission that the case was urgent. It rejected various types of harm that Flynn alleged it would suffer (such as its ability to re-establish a higher price than that mandated by the CMA's directions if it were successful on the appeal) but accepted that Flynn would suffer significant irrecoverable financial harm both in absolute terms and in relation to its size. It rejected the CMA's argument (based on EU jurisprudence) that Flynn had to show something more, namely that the viability of its continued existence was threatened to demonstrate irreparable harm.

Thus the nub of the issue in terms of the CAT's decision came down to the effect on competition or third party interests and whether these outweighed the degree of irrecoverable financial harm to Flynn. Of greatest importance in this regard was the potential harm to patients from the impact on other services resulting from the diversion of funds from relevant NHS entities to pay higher prices for Flynn's product in the period until the appeal could be resolved. Some evidence to this effect was provided from some relevant NHS entities and the CAT heard argument from the Department of Health.

The Tribunal found that the grant of interim relief would take funds out of the NHS which would otherwise be used to treat patients in need of care in the period pending the appeal. This would cause irreversible harm to the patients in question. The Tribunal found that this non-financial harm was detrimental to the public interest, and was the very harm which the Decision was intended to prevent. The Tribunal ruled that this outweighed any harm which the Directions would cause to Flynn. It also identified difficulties in damages as a remedy, including applying the cross-undertaking which Flynn had proposed to an organization as complex as the NHS.

Conclusion

The present judgment is an interesting example of the exercise of the CAT's powers to grant interim relief pending an appeal. The outcome unsurprisingly seems to have been highly driven by the risk of harm to patients, which the CAT considered outweighed other considerations. To some extent however the case raises more questions than it answers about the CAT's new powers to grant interim relief, and in particular how significant does harm have to be if the risk of some irreparable financial harm must be regarded as inevitable

because of the general absence of a cross undertaking in damages? Clearly interim relief is normally intended to 'hold the ring' pending the delay in finally determining a case. In this case Flynn argued that the fact that the CMA's investigation had taken approximately four years should be taken into account in assessing the strength of the CMA's argument that harm to patients was occurring and the directions should take effect immediately. In the face of evidence of the risk of patient harm it is unsurprising that this point was not accepted by the CAT. Given the potential harm to patients there is a separate question however as to whether the CMA should itself have imposed interim measures at an earlier stage pending the outcome of its investigation using its powers under section 35 of the CA98.[3] The context of such a decision is of course different to the decision which faces the CAT under Rule 24. Not only does the issue arise before any decision has been taken, but the harm may be less immediately apparent and there is an understandable reluctance to intervene in markets prematurely. Also adopting such an interim decision will have resource implications for the main investigation. This power has however existed since 2000 but has for all practical purposes never been used by the CMA or its predecessors.[4] It is unclear whether there will ever be a case where it will be employed. If there was a case for justifying its deployment, a case with direct implications for the health of patients might have a claim to being an appropriate candidate. Consistent with the amendments to Rule 24, section 35 CA98 has also been amended to refer to a "significant harm" threshold rather than "irreparable harm". Thus the nature of the harm required for the purposes of Rule 24 also has possible implications for the CMA's ability to intervene under section 35CA98. Whether the legislator's intention by tinkering with the definitions in this area was to lower or raise or leave unchanged the threshold for intervention under section 35 is not immediately clear. At any rate, the CMA's submissions at least as recorded by the CAT suggest it considers "significant harm" at least in the context of an application for interim measures to suspend a direction to mean harm that is both "irreparable" and "substantial".

[3] See section 35 of the Competition Act 1998, in which "serious and irreparable damage" has also been substituted with "significant damage".
[4] In one case a decision was issued and then withdrawn.

Ronit Kreisberger acted for Flynn Pharma

Rob Williams acted for the Competition and Markets Authority

Brendan McGurk acted for the Department of Health.

The Comment made in this case note are wholly personal and do not reflect the views of any other members of Monckton Chambers, its tenants or clients.

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