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Lessons from Recent Competition Appeal Tribunal Pharma Appeals

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Venue:	Bristows LLP, 100 Victoria Embankment, London EC4Y 0DH
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Introduction

There are several ongoing or recently concluded pharmaceutical cases in the Competition Appeal Tribunal (CAT), which are addressed in turn in this presentation.

Liothyronine[1]

This was an abuse-only case concerning a second-line treatment (fallback therapy) for hyperthyroidism used to treat a relatively small cohort of patients. The drug is difficult to manufacture.

At the beginning of the infringement period, there was only one supplier (Advanz). At the beginning of the period, the price per pack was £4.05. Following a series of changes in ownership of the Marketing Authorisation, 63 price increases resulted in a final price of over £200 per pack. The CMA was concerned about the price rise period before plateaus.

Hydrocortisone[2]

This drug is used for patients whose adrenal glands do not produce sufficient hormones. Approximately 900,000 packs are sold per year. During the infringement period, the price for a 100mg pack rose from less than £1 to £80, and the price for a 200mg pack rose from under £1 to £102.

The case concerned an abuse of dominance, excessive/unfair pricing and an unlawful agreement not to price competitively.

A judgment has been given on abuse the aspect of the case, but a judgment on the unlawful agreement is still pending.

Phenytoin II[3]

This was an abuse-only case concerning a second-line treatment for epilepsy. The patients who were stabilised on the drug received medical attention not to change drugs, nor could they change to a different presentation of Phenytoin. This called into question the continuity of supply and whether the patients were captured.

Pfizer was the main supplier, with Teva also supplying. When Pfizer sold the Marketing Authorisation to Flynn, prices increased by a factor of between 7 and 27 during the dominant period.

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[1] 1411/1/12/21 Advanz Pharma Corp v Competition and Markets Authority
[2] 1407/1/12/21 Allergan plc v Competition and Markets Authority
[3] 1524/1/12/22 Pfizer Inc. and Pfizer Limited v Competition and Markets Authority

The case was heard in the Court of Appeal before being remitted back to the CMA. There was a further CAT hearing in 4Q 2023 for which the judgment is pending.

Prochlorperazine[4]

This was a case concerning an alleged unlawful agreement by which a competitor was paid not to launch a product, allowing prices to increase. The competitor had taken steps to enter the market so were a viable competitor but were then incentivised not to launch. During a six-year period, the price of Prochlorperazine increased by 700%.

Vifor

This case is a pending CMA investigation into abuse (disparagement). There is a parallel case at the European Commission level. The case concerns a pharmaceutical manufacturer that allegedly abusively disparaged a competing iron treatment.

Substantive issues

Unfairness

There was a significant amplification of the case law in the findings of *Phenytoin I,*[5] putting flesh on the bones of the *United Brands*[6] test.

Hydrocortisone adds new 'Cases 1-3' rubric which states unfair pricing is about reasonable and proportionate balance between manufacturers on one hand and users on the other. Unfairness cases, therefore, can be broadly categorised as:

- **Case 1:** High prices are justified by superior efficiency, granting a cost advantage over other manufacturer. In this case the extra margin is valid.
- **Case 2:** If a product has "distinctive value", the producer is entitled to charge a premium – although it may not be an unlimited premium.
- **Case 3:** A producer surplus is generated without added customer value: this is presumptively unfair.

First issue: where do cases 1-3 fit in context of *Phenytoin I*? Distinct from the principles? Gloss on them? Something else?

The Judge in *Hydrocortisone* recognised that they are practically, legally, economically difficult questions.

Is the rule of thumb, then, that prices should be tethered to 'cost plus' and the onus is on the appellate to justify a departure? There is also an open question as to whether Cases 1-3 will be applied in the CAT and across competition litigation more widely.

The CMA already considers costs plus and a matrix of other evidence (for example, objectives and intentions of people and firms involved and the effects on consumers) before reaching a decision.

Tribunal is endeavouring to say *United Brands* is an old case, with a lack of legal certainty (notwithstanding the clarifications made in *Phenytoin I*) relating to pricing, so greater precision and real-world applicability is needed. Query, however, whether Cases 1-3 could be seen as over-prescriptive.

Liothyronine

During the monopoly phase, prices increased in stages from £5 to £250. The price fell after the end of the infringement period to between £40 and £150, however this was still multiples of the CMA benchmark for a fair price.

The supplier argued that "workable competition" allowed for prices that were orders of magnitude higher than the CMA fair price. The CAT said that this was a strong argument but that the peak of £250 during the

[4] 1432/1/12/22 Advanz Pharma Corp v Competition and Markets Authority
[5] 1275/1/12/17 Flynn Pharma Ltd and Flynn Pharma (Holdings) Ltd v Competition and Markets Authority [2018] CAT 11 at paragraphs 442-443
[6] United Brands Company and United Brands Continentaal BV v Commission of the European Communities 27/76 1978

infringement period had a contaminating effect on pricing that continued latently post-infringement, that prices had not (yet) stabilised, and that the post-infringement price reductions observed (and their speed of decrease) were not typical of other generics price decreases. Liothyronine was therefore an outlier price so not consistent with workable competition.

The appellants are seeking permission to appeal. They argue:

- The principle of price stabilisation is subjective and not provide enough legal certainty. The CMA argues, however, that it was common ground that it would take a certain amount of time for prices to be "decontaminated" and that there was no sharp dividing line for when post-entry price becomes relevant as a comparator.
- An objective test should instead have been applied, considering prices consistent with workable competition in different scenarios.
- It was wrong as a matter of law to say high price to incentivise entry is abuse. Incentivising market entry is pro-competitive and can serve consumers' interests. If there is a concern as to legal certainty, the answer to the question of what price would incentivise entry is to gather evidence from potential entrants. (there was no conflict In *Liothyronine* as to what priced would incentivise entry).

Market definition/dominance

In *Hydrocortisone,* the CAT overturned the CMA market definition but upheld its case on dominance. They concluded that the Hydrocortisone market is one in which many stakeholders (such as doctors, pharmacists and patients) don't know or don't care about the price. As such, applying standard SSNIP analysis is not straightforward. The CAT therefore said that it does not consider the actual prices charged and instead uses the flat prescription fee price.

The CAT analysis also means that dominance must be considered substantial period by substantial period, and not simply across the infringement period as a whole (where there were multiple different owners and prices). In this case, there were multiple years where firms were in competition, meaning that the market shares of the dominant firms had been reduced by up to 50% for some periods. Bu the CAT found that the high market shares were consistent with dominance for the whole period.

Agreement issues

Following *Paroxetine*[7] and *Lundbeck*[8], it is harder to argue that non-compete agreements between potential or actual competitors is not infringement by object. Disputes will therefore likely centre around whether: (i) there was an agreement at all and (ii) the agreement was the one the CMA identified.

Policy issues for the pharmaceutical industry

The CAT has been critical of cases which, for the most part, originate in regulatory failure. Ad-hoc litigation for abusive practices is a less effective long-term enforcement strategy than ensuring a systematic basis to ensure consistent and fair pricing in the first place.

In *Hydrocortisone,* the CAT was critical of critical of the Department of Health and Social Care's failure to use price control powers, its use of monopoly pricing to calculate the Drug Tariff price, and the unintended anticompetitive consequences of the Orphan Drug regime (which include an extended effective patent life, meaning that competitors couldn't enter the market for a significant amount of time).

There may also be unintended consequences of the CAT being forced to make decisions on issues in pharmaceutical cases without proper input from the government/DHSC. For example, the absence of DHSC witnesses in appeals is problematic – the DHSC has made no attempt to explain how competition is supposed to function and why it isn't exercising its regulatory price control powers, instead letting the CMA bring ad hoc claims.

[7] 1251/1/12/16 Generics (UK) Limited Glaxosmithkline PLC and Others v Competition and Markets Authority [2021] CAT 9

[8] 1415/5/7/21 The Secretary of State for Health and Social Care & Others v Lundbeck Limited & Others

Process – including strategic and tactical considerations

Concurrent evidence

This is a process widely used in cases such as those addressed in this meeting (including Liothyronine, Hydrocortisone and Phenytoin). Concurrent evidence involves the simultaneous testifying of expert witnesses, for example in a hot tub panel. This results in the experts giving evidence on issues in which they have the greatest interest or experience. This can affect the rights of the parties to the dispute as the CAT has shown a tendency to cut short the cross-examination of the experts on issues covered in the hot tub panels. Evidence can therefore be curtailed or limited.

However, this method can reduce the burden on the parties to exhaustively deal with every allegation if it can instead be dealt with in the hot tub.

"Teach-ins"

This is a positive process as it can be quite neutral with respect to the content. For example, it can be used to explain how regression analysis works in the context of the case. It can also be used to introduce new material which may increase the scope of the issues. It therefore needs judicial control to be exerted in order to maintain the scope.

Role of cross-examination and CAT

There may be some practical difficulties with cross-examination due to the time taken up with hot tubs and teach-in. More of the latter will reduce the significance of, and time for, cross-examination.

"Ambulatory drafts"

This is a process by which the parties attempt to agree common background facts which the CAT can use as a basis for its judgment. This approach was tried in *Liothyronine* and *Hydrocortisone*. The parties attempted to agree but the CAT stated that it did not find the ambulatory drafts particularly helpful due to the number of qualifications given. The CAT said that it probably would not use them again in this context.