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**CMA Pharma Investigations on Appeal**  
**Learnings from recent CAT judgments in**  
***Hydrocortisone and Liothyronine***

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Robert O'Donoghue KC and Hugo Leith

## AGENDA

- Background to cases
- Substantive issues:
  - Abuse
  - Agreement
  - Market def/dominance
- Policy issues for pharma
- Process (inc strategic and tactical considerations)
- Q&A

## CAT Appeals – Background

- *Liothyronine* (abuse only)
  - CAT judgment rendered, CA appeal pending
- *Hydrocortisone* (abuse & agreement)
  - CAT abuse judgment rendered
  - CAT judgment on agreement still pending
- *Phenytoin II* (abuse only)
  - Appeal heard in 4Q 2023, judgment pending
- *Prochlorperazine* (agreement only):
  - Appeal heard in summer 2023, judgment pending

## CMA Pending Investigations

1. Vifor pharmaceutical (abuse (disparagement case))
2. Parallel case at Commission level
3. Allegation is that Vifo have abusively disparaged a competing iron treatment, Monofer, by making misleading claims about the safety of Monofer and Vifor Pharma's own product, Ferinject, designed to hinder competition from a rival product and promote Ferinject.

## LEGAL TEST FOR UNFAIRNESS

- Legal test clarified in *Phenytoin I* by CAT (§442-443) and CA (§97) – essentially amplification of *United Brands*
- *Hydrocortisone* adds new Cases 1-3 rubric that seeks to nest producer and consumer surplus balance:
  - Case #1: ‘high’ prices justified by superior efficiency
  - Case #2: ‘high’ prices (potentially) justified by “distinctive value”
  - Case #3: generation of producer surplus without added customer value
- Issues arising under Case #1-3 rubric

## LIOTHYRONINE: WORKABLE COMPETITION (1)

- Prices during monopoly phase increased over time, in stages, from £5 to £250.
- Following end of infringement period, there were two actual new entrants and two potential entrants.
- Prices, over post-infringement period of 3 years +, fell from £250 but remained many multiples above CMA benchmark for fair price (£5-20): prices ranged from £40 to £150.
- Domco argued that this showed that “workable competition” yielded prices far above CMA benchmark and that that benchmark was therefore wrong.
- CAT rejected Domco argument saying: (a) post-infringement prices “contaminated” by excessive infringement period prices; (b) generic markets take a few years to stabilize following entry; (c) Lio price reductions post-infringement not typical of “average” for generic drugs; and (d) Lio was enormous outlier with most other generic comparator drugs.

## LIOTHYRONINE: WORKABLE COMPETITION (2)

- Issues raised by parties seeking to appeal CAT judgment in *Liothyronine* appeal (NB disputed by CMA):
  - Test based primarily on a subjective and nebulous test that prices had not yet “*stabilised*” (due to “*contamination*” from the past high price levels) subjective and incompatible with the principle of legal certainty. Quasi-criminal penalty cannot depend on some arbitrary assessment of whether a stable pricing nadir has been reached.
  - CAT should instead have applied the objective and simple test that considers prices consistent with workable competition:
    - In the absence of a dominant position, collusion, and capacity constraints;
    - Where new entry gave rise to competitive benefits for consumers in the market: (a) new doses of Liothyronine; (b) longer shelf-life products; (c) non-allergic product versions; (d) a capsule version of the product; and (e) additional sources of manufacturing capacity that would improve security of supply.
- CAT wrong to find that price levels need to incentivise market entry “*would be incorrect as a matter of principle.*” (§319) Appellants argue that ignores the importance of protecting the competitive process as part of competition law – that, too, serves consumers’ interests. High prices can promote entry – dominant firm should not have duty to foreclose entry.

# MARKET DEF/DOMINANCE

- *Hydro* overturned CMA market definition but upheld case on dominance
- CAT analysis significant potential implications:
  - SSNIP that does not rely on actual prices but uses flat prescription fee as basis for SSNIP assessment of hypothetical consumer (§243)
  - Deprecated monolithic approach in favour of need to assess dominance in each period (§265).
  - “*Primary regard*” to market shares on dominance (50%+) rather than evidence of competition (§292)

## AGREEMENT ISSUES

- Two agreement cases – *Hydrocortisone* and *Prochlorperazine* – *sub judice* so limits to what can be gleaned
- Some pointers:
  - *Post-Paroxetine* and *Lundbeck* hard(er) to argue that non-compete between potential or actual competitors is not object
  - Battleground is therefore likely to be over whether: (i) there was an agreement at all; and (ii) was the agreement the one the CMA identified
  - Likely to be important in practice in most cases to call witnesses who can attest to contemporaneous documents/facts

## PHARMA POLICY ISSUES

- Cases for most part originate in regulatory failure
- In *Hydro* CAT critical of:
  - DHSC failure to use price control powers (§274(1))
  - Using Drug Tariff price calculated by reference to monopoly price (§274(2))
  - Unintended anticompetitive consequences of Orphan Drug regime (§274(3))
- Portfolio pricing defence needs evidence (*Hydro*, §352)
- Risks of appeals ‘cherry picking’ complex waterbed regime for pharma
- Absence of DHSC witnesses from appeals problematic

# PROCESS

## 1. Concurrent evidence

- Widely used in *Liothyronine, Hydrocortisone, Phenytoin II*
- Pros and cons

## 2. “Teach-ins”

- Used in *Phenytoin II*
- Pros and cons

## 3. Role of cross-examination and CAT

## 4. “Ambulatory drafts”

- Used in *Liothyronine, Hydrocortisone* but effectively jettisoned