



COMPETITION APPEAL TRIBUNAL

NOTICE OF AN APPEAL UNDER SECTION 46 OF THE COMPETITION ACT 1998

Case No: 1413/1/12/21

Pursuant to rule 14 of the Competition Appeal Tribunal Rules 2015 (S.I. 2015 No. 1648) (“the Tribunal Rules”), the Registrar gives notice of the receipt of an appeal on 6 October 2021, under section 46 of the Competition Act 1998 (“the Act”), by Auden Mckenzie (Pharma Division) Limited (“Auden”); and Accord UK Limited (“Accord-UK”), formerly known as Actavis UK Limited (“Actavis-UK”) (together “Auden/Actavis”), against a decision of the Competition and Markets Authority (“the CMA”) dated 15 July 2021, entitled *Hydrocortisone Tablets. Excessive and unfair pricing and anti-competitive agreements* (“the Decision”). Auden/Actavis are represented by Macfarlanes LLP, 20 Cursitor Street, London EC4A 1LT (reference: Andrew Morrison / Matthew Redfern / Cameron Firth).

The Decision follows three separate CMA investigations into the sale of hydrocortisone tablets, later combined into one investigation, which began on 8 March 2016. Hydrocortisone tablets are an essential, life-saving prescription-only medicine used for the treatment of adrenal insufficiency.

The Decision finds Auden/Actavis-UK liable for four infringements in relation to the sale of hydrocortisone tablets:

- a. Abuse of dominant position by charging excessive and unfair prices, thereby infringing the Chapter II prohibition under the Act: between 1 October 2008 and 31 July 2018 in relation to the supply of 10mg hydrocortisone tablets (the “10mg Unfair Pricing Abuse”), and between 1 October 2008 and 8 January 2017 in relation to the supply of 20mg hydrocortisone tablets (the “20mg Unfair Pricing Abuse”), (together the “Unfair Pricing Abuses”, as defined in the Decision); and
- b. Entering into anti-competitive agreements (the “Agreements”, as defined in the Decision), thereby infringing the Chapter I prohibition under the Act: with Waymade (namely Waymade plc and Amdipharm UK Limited), between 11 July 2011 to 30 April 2015, in relation to the supply of 20mg hydrocortisone tablets (the “20mg Agreement”, as defined in the Decision to include an alleged “common understanding” that Waymade would not enter the market with its own product), and with Waymade, between 23 October 2012 and 30 October 2012, and then AMCo, between 31 October 2012 and 24 June 2016, in relation to the supply of 10mg hydrocortisone tablets (the “10mg Agreement”, as defined in the Decision to include an alleged “common understanding” that Waymade/AMCo would not enter the market with their own product, not contained in and separate from the two written agreements entered into between Auden and Waymade/AMCo).

The CMA has decided to impose fines on Actavis-UK (now Accord-UK) in the total amount (before application of the statutory cap) of £155.2 million for the Unfair Pricing Abuses and £66.0 million for the Agreements.

Auden/Actavis-UK challenge the CMA’s findings as to liability in respect of the Unfair Pricing Abuses and the 10mg Agreement and the fine imposed by the CMA in respect of the Unfair Pricing Abuses and both Agreements. They advance the following grounds of appeal:

In relation to the Unfair Pricing Abuses:

1. The CMA has erred in its assessment of market definition, by treating the market as being at the level of a single compound in instant release form (i.e., by adopting a market definition even narrower than the level of ATC5 and not ATC3 or at narrowest ATC4) and/or by failing to include

other clinical substitutes including Plenadren, other hydrocortisone forms, and prednisolone (Ground 1).

2. The CMA has erred in its assessment of dominance, by: failing to have regard to countervailing buyer power on the part of the NHS, arising from the Department of Health's powers under sections 261-266 of the National Health Services Act 2006 and its role in exercising monopsony pricing powers in respect of hydrocortisone tablets; and in any event, failing to find that dominance ended in July 2015 following the independent entry of Waymade (with a 20mg product), alternatively in October 2015 following the entry of Alissa Healthcare Research Limited (with a 10mg product), alternatively in March 2016 following the entry of Resolution Chemicals, alternatively in March/April 2016 following the entry of Bristol Laboratories, alternatively April/May 2016 following the entry of AMCo with its Aesica product.
3. The CMA has erred in its assessment of abuse, by adopting a cost-plus analysis which fails properly to compare the price charged against any other factors which might otherwise serve to justify the price charged as fair and not abusive; had it done so, it would have found that the prices charged by Auden/Actavis-UK were not unfair. In particular, the CMA failed properly to consider the pricing of appropriate comparators (in particular Plenadren and Hydrocortistab). It was particularly imperative that the CMA inform its cost-plus analysis by reference to appropriate comparators given the economic value to be accorded to what the CMA acknowledges is a life-saving drug which would not have been available at all if Auden had not taken over the licence in 2008 and the fact that, had Auden/Actavis-UK charged the cost plus prices as determined by the CMA for hydrocortisone tablets at the time, its entire portfolio of pharmaceuticals would have been heavily loss-making for a number of years.
4. The CMA has erred in its assessment of duration, by failing to have regard to the imminent prospect of independent generic entry as required by the case-law.

In relation to the 10mg Agreement:

5. The CMA erred in finding a 'by object' infringement in circumstances where the written contracts containing the 10mg Agreement were not on their face anticompetitive: (i) on the basis of a presumption that single generic entry would lead to a precipitous decrease in prices; (ii) by inferring the existence of a "common understanding" without having conducted a proper examination of the real conditions of the functioning and structure of the market; and (iii) by failing to recognise that the 10mg Agreement contains no volume caps.
6. The CMA has erred in its assessment of duration by finding that any "common understanding" continued beyond 29 May 2015 when Actavis completed its acquisition of Auden (and hence has erred in finding that Actavis-UK is a primary infringer) in that the CMA has failed to show that following that date Auden/Actavis-UK had any knowledge of and so any intention to agree or comply with the supposed unwritten terms agreed between the previous personnel.
7. The CMA erred in its assessment of duration by finding that the 10mg Agreement reached with AMCo lasted until 24 June 2016 instead of March 2016, when AMCo resolved to enter with its own product, alternatively April or May 2016, when AMCo actually entered, and so in each case the supposed 'object' of the agreement – to prevent AMCo's entry – was exhausted.
8. To the extent that any penalty falls to be imposed at all, and any penalty is appropriate for the 20mg Agreement, the penalty imposed on Actavis-UK (now Accord-UK) by the CMA is manifestly disproportionate, based on numerous errors of analysis and must be reduced. In particular, the CMA has erred in fining Actavis-UK (now Accord-UK) multiple times its statutory cap.

Any person who considers that he has sufficient interest in the outcome of the proceedings may make a request for permission to intervene in the proceedings, in accordance with rule 16 of the Rules.

Please also note that a direction of the President is currently in place as to the electronic filing of documents: see paragraph 2 of the [Practice Direction](#) relating to Covid-19 published on 20 March 2020. Therefore, a request for permission to intervene should be sent to the Registrar electronically, by email to registry@catribunal.org.uk, so that it is received within **three weeks** of the publication of this notice.

Further details concerning the procedures of the Competition Appeal Tribunal can be found on its website at www.catribunal.org.uk. Alternatively, the Tribunal Registry can be contacted by telephone (020 7979 7979) or email (registry@catribunal.org.uk). Please quote the case number mentioned above in all communications.

Charles Dhanowa OBE, QC (Hon)
Registrar

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