



COMPETITION APPEAL TRIBUNAL

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

Case No: 1411/1/12/21

Pursuant to Rule 14 of the Competition Appeal Tribunal Rules 2015 (S.I. No 1648 of 2015) (the “Rules”), the Registrar gives notice of the receipt of an appeal on 15 September 2021 under section 46 of the Competition Act 1998 (the “Act”), by Amdipharm UK Limited, Amdipharm Limited, Advanz Pharma Services (UK) Limited, and Advanz Pharma Corp. Limited (together, “Advanz”) against a decision of the Competition and Markets Authority (the “CMA”) dated 15 July 2021 in Case 50277 entitled *Hydrocortisone tablets - Excessive and unfair pricing and Anti-competitive agreements* (the “Decision”). Advanz is represented by Morgan, Lewis & Bockius UK LLP of Condor House, 5-10 St. Paul’s Churchyard, London EC4M 8AL (reference: Frances Murphy/Leo Theodosiou).

Auden Mckenzie (“Auden”) and AMCo (a company now owned by Advanz) were parties to written supply agreements whereby AMCo sourced 10mg hydrocortisone tablets (“HT”) from Auden pending the completion by AMCo of the development of its own 10mg HT. Auden’s 10mg HT is a medicine licensed to treat adrenal insufficiency in adults and children (‘full indication’ 10mg HT). As a result of the operation of orphan drug regulations, Auden was effectively conferred the exclusive right to supply full indication 10mg HT in the UK, and all subsequent applicants for a marketing authorisation (“MA”) for 10mg HT could not be permitted a licence for full indication 10mg HT, instead they were only permitted a ‘reduced indication’ MA for the treatment of adrenal insufficiency in children (children’s 10mg HT).

The Decision finds, insofar as it concerns Advanz, that the legally permissible written supply agreements between Auden and AMCo for Auden’s full indication 10mg HT were accompanied by an unwritten agreement whereby, for an unbroken period from 31 October 2012 to 24 June 2016 (“Infringement Period”), Auden paid AMCo not to enter the market independently with its own, children’s 10mg HT (“10mg Agreement”).

Further, the Decision finds that this 10mg Agreement had as its object the restriction of competition and as such was unlawful contrary to section 2 of the Act and imposes fines of £7.7 million on Advanz and £35.1 million on Cinven, Advanz’s former owner, in respect of which Advanz is jointly and severally liable for £14.2 million.

Advanz appeals the Decision. The principal grounds of appeal on which Advanz relies are:

1. There was no 10mg Agreement. There is no evidence of an unwritten understanding on the part of AMCo that it was being paid by Auden to stay out of the market. On the CMA’s own case, Auden actively sought to exclude AMCo by pursuing a highly aggressive marketing campaign against it to draw the attention of pharmacies, wholesalers and regulators to the fact that AMCo’s children’s product was inferior. Furthermore, and in any event, AMCo actively pursued numerous routes to market with a 10mg HT and at all times genuinely sought to enter the market with its own children’s 10mg HT which AMCo did as soon as it was supplied with compliant product by its developer and its customers expressed an interest in purchasing it. On the facts properly construed, there was also no value transfer from Auden to AMCo.
2. There was no 10mg Agreement but even if there was (which is not accepted), it did not amount to a restriction of competition by object. This includes because: (a) the written supply arrangements between Auden and AMCo which included exclusive purchasing and non-compete obligations are expressly accepted by the CMA as not being restrictive of competition, but yet the CMA does not address how the alleged unwritten 10mg Agreement could have impermissibly restricted competition; (b) AMCo’s children’s 10mg HT did not compete with Auden’s full indication 10mg

HT product and it would have been a breach of pharmaceutical regulations for them to have been represented as interchangeable; (c) even if the two medicines did compete (which is not accepted), viewed objectively such an agreement as the 10mg Agreement would not have as its object a significant loss of competition between Auden and AMCo.

3. The CMA has erred in imposing a fine on Advanz. There should be no fine on Advanz (or it should be greatly reduced) including because, even if the 10mg Agreement did exist (which is not accepted), the evidence shows that Advanz did not act intentionally or negligently and, in any event, the CMA's calculation of Advanz's fine is vitiated by material errors of law and factual assessment.

As regards the relief sought, Advanz requests that:

- a. the Decision be set aside in whole or in part so far as it concerns Advanz;
- b. the fine imposed on Advanz be annulled or, in the alternative, reduced significantly; and
- c. the CMA be ordered to pay Advanz's costs incurred in connection with the appeal.

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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