The assessing science authority and proportionality in judicial review (R (on the application of Actegy Ltd) v Advertising Standards Authority)

12/09/2019

Commercial analysis: In a case concerning the advertisement of electrical stimulation products for feet, the court was willing to entertain grounds for judicial review on a composite basis of irrationality and the principle of proportionality. The court found that the Advertising Standards Authority's (ASA) assessment and conclusions—that the scientific evidence supplied in support of the medical claims as advertised was inadequate—were rational and proportionate. Written by Max Schofield, barrister, at 3PB Barristers, London.

R (on the application of Actegy Ltd) v Advertising Standards Authority Ltd [2019] EWHC 2374 (Admin), [2019] All ER (D) 23 (Sep)

What are the practical implications of this case?

Notwithstanding the uncertainty of the principle of proportionality as a ground for judicial review, the court in *Actegy* was willing to hear and decide on proportionality arguments in relation to the ASA and Directive 2005/29/EC, the Unfair Commercial Practices Directive (UCPD). This could be seen as extending judicial review on the grounds of proportionality beyond infringements of fundamental rights as discussed in recent Supreme Court case law (see Lord Kerr in *Keyu v Secretary of State for Foreign and Commonwealth Affairs* [2015] UKSC 69, [2016] 4 All ER 794).

However, even if *Actegy* has unlocked or opened the door to the broader application of the EU law concept in judicial review proceedings, the door is likely no more than narrowly ajar for the following reasons—(i) the grounds were pleaded under proportionality 'and/or' irrational, (ii) recital 6 of the UCPD explains that the Directive seeks the protection of consumers from material consequences of unfair practices (specifically) in line with the principle of proportionality, (iii) the court was insistent that conformity with the UCPD would not offend the principle of proportionality and such challenges must fail unless there was a departure from the Directive and there was interference with the EU law rights. Although this bipartite requirement is given only cursory lip-service, it reflects the current authority.

Readers may also be surprised as to the breadth of discretion afforded to the ASA to assess medico-scientific research under their remit of advertising. As noted by Thirlwall J in *R (Coys of Kensington) v ASA* [2012] EWHC 902 (Admin), [2012] All ER (D) 161 (Feb), 'the value of [the ASA's] experience and expertise should not be underestimated' but in this case, the decision as to the adequacy of scientific trials was made without a relevant expert (independent or otherwise). Advisors should remember that CE certification in itself does not constitute evidence for the purpose of rule 12.1 of the UK Code of Non-broadcast Advertising and Direct & Promotional Marketing (CAP Code) and be aware of the high standard of evidence required to avoid potentially misleading actions.

Although not discussed in this case, pedants might note that Article 12 of the UCPD requires 'sufficient' evidence to be provided to substantiate a claim, if evidence is demanded by the authorities. However, section 218A of the Enterprise Act 2002 and rule 3.7 of the CAP Code requires 'adequate' substantiation. There may be scope for interpretation as one may read Article 12 of the UCPD as requiring a trader to produce quantity of evidence whereas the CAP Code and the ASA ruling in this case (and in other ASA rulings—eg ASA Ruling on Neuronix Medical Ltd, 21 March 2018) require production of quality evidence. Both terms are used seemingly interchangeably in the ASA ruling in relation to Actegy Ltd of 11 April 2018.

What was the background?

The claimant manufactures devices that provide electrical stimulation to the soles of the feet with the stated purpose of achieving potential therapeutic benefits such as improving circulation and reducing swelling. One particular model of said devices (Revitive DX) was advertised in the Daily Mail and The Times in early 2017. The advertisements made a number of claims concerning relief from aching legs, reduced foot swelling and pain, and a boost in circulation. The ASA received a complaint concerning whether the claims could be substantiated. The claimant then supplied the ASA with a Clinical Evaluation Report (CER) and other scientific studies. The ASA published their ruling upholding the complaint in April 2018.

The ruling was critical of the adequacy of evidence in support of the claims, finding that there was evidence of an effect on circulation but there were uncertainties concerning factors such as frequency and duration of use, and a lack of quality randomised blinded trials. The advertisement therefore breached CAP Code rule 3.1 (misleading advertising), rule 3.7 (substantiation) and rule 12.1 (medical devices and health-related products).

The claimant brought judicial review proceedings on three permitted grounds asserting that the ASA test was 'disproportionate and/or unreasonable', that the approach and standard for assessing substantiation was disproportionate and/or irrational, and that the conclusion was irrational.

Although not discussed in the judgment, proportionality as a ground for judicial review has been the matter of some academic and case law debate. It has generally garnered support in cases concerning interference with fundamental rights (for example, see Lord Carnwath in *Youssef v Secretary of State for Foreign and Commonwealth Affairs* [2016] UKSC 3, [2016] 3 All ER 261 and Lord Kerr in *Keyu v Secretary of State for Foreign and Commonwealth Affairs* [2015] UKSC 69, [2016] 4 All ER 794).

What did the court decide?

The judgment sets out the applicable EU regulatory legislation including Directive 93/42/EEC, the Medical Devices Directive, and the UCPD. The UCPD is a harmonisation Directive protecting consumers from material consequences of unfair practices, subject to the principle of proportionality. Article 12 of the UCPD allows for member states to require a trader to furnish evidence as to the accuracy of factual claims, and to consider a factual claim inaccurate if the evidence (as demanded) is not furnished or deemed insufficient.

The traditional grounds for judicial review were set out in the judgment before opining that pleadings based on proportionality were destined to fail as the UCPD is EU law which necessitates the furnishing of evidence and the prohibition of misleading advertising. However, the court included a caveat—that the claim must fail unless the claimant could show the ASA departed from the requirements of the UCPD contrary to its EU law rights. It was on this basis that the court assessed the ASA's evidential requirements. It found that the ASA's approach in relation to the test to be applied to medical devices (the first ground) was proportionate as it did not depart from the UCPD requirements.

In relation to the second and third grounds concerning the approach to substantiation in this specific case, the court had the benefit of expert evidence for both parties. The claimant explained that randomised blind trials are difficult or impossible with devices involving obvious physical intervention such that patients will know if they are in the control group or not. The ASA applied standards which were unreasonably exacting, especially in this scientific field. They submitted that the CER was correct to conclude that there was sufficient evidence to support the claims.

The ASA expert disagreed, arguing there was scope for higher quality trials of such devices. There was also concern over the scientific studies using a different but similar model of the device rather than the model advertised. He concluded that the device may temporarily improve circulation but there was insufficient evidence to conclude a reduction in swelling or pain. Interestingly, he criticised the ASA for not appointing an independent expert to review the evidence from the outset.

The court, stressing caution in relation to evidence which was not before the decision maker at the time, held that the conclusions considered the totality of the evidence and were rational. The judge further added that even if the principle of proportionality test had been applied, the court would have found that the ASA's analysis was in pursuit of a legitimate aim, was a suitable means of pursuing that objective, and was necessary in that it was not more restrictive than an alternative means (no such alternative having been identified).

Case details

- Court: High Court, Queen's Bench Administrative Court (London)
- Judge: Charles Bourne QC (sitting as a deputy judge of the High Court)
- Date of judgment: 09/09/2019

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