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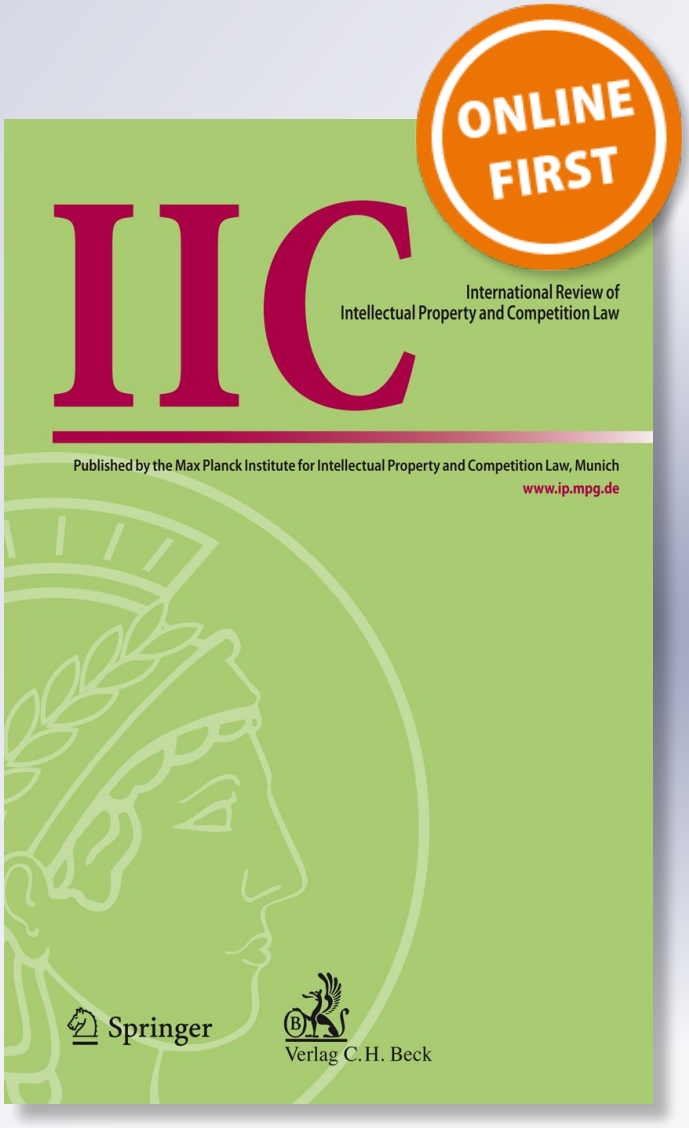

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OPINION

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On December 7, 2016 the UK Competition and Markets Authority (CMA) fined Pfizer £84,196,998 and Flynn £5,164,425, for a total of £89,361,425, for abuse of dominant position by excessive pricing of a pharmaceutical product used to treat epilepsy.[1] On June 7, 2018 the UK Competition Appeal Tribunal (CAT) rendered a decision on consolidated appeals by Pfizer and Flynn that affirmed in part, and reversed and remanded (pending briefing) in part, that decision by the CMA.[2]

Pfizer and Flynn had together worked out a complex scheme designed to take phenytoin sodium capsules out of the UK's system of price controls. This involved a uniquely British process referred to as "debranding" pursuant to which Pfizer transferred its UK marketing authorization for its branded phenytoin sodium capsules, known as "Epanutin", to a middle-person, Flynn, without the associated trademark. Flynn was not subject to price controls that had been applicable to Pfizer's branded drug, and this allowed it to dramatically increase the price. Overnight, the price of the "generisized" identical drug to the NHS increased from £2 million to £50 million per year. Pfizer was (and via Flynn remains) the sole supplier of the anti-epilepsy drug or "AED" in the UK, with the NHS a "captive market".

[1] *Decision of the Competition and Markets Authority, Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK*, Case CE/9742-13, 7 December 2016 (non-confidential/public text), https://assets.publishing.service.gov.uk/media/594240cfe5274a5e4e00024e/phenytoin-full-non-confidential-decision.pdf [hereinafter "CMA Decision"].

[2] *Flynn Pharma & Pfizer v. Competition and Markets Authority*, in Competition Appeal Tribunal, [2018] CAT 11, Case Nos: 1275-1276/1/12/17, 7 June 2018, http://www.catribunal.org.uk/237-9616/1274-1-12-16-IR-Flynn-Pharma-Limited-and-Another.html [hereinafter "CAT Decision"].

F. M. Abbott (✉)
Edward Ball Eminent Scholar Professor of International Law, Florida State University College of Law, Tallahassee, USA
e-mail: fabbott@law.fsu.edu

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The evidence gathered by CMA from Pfizer and Flynn showed that Pfizer executives knew exactly what they were doing in terms of "fleecing" the NHS,[3] and some in fact expressed misgivings at the outset of the process, particularly as the NHS was in the midst of substantial budget tightening. As stakeholders in the NHS observed, the dramatic increase in expenditure on phenytoin sodium capsules forced cutbacks for other areas of British healthcare.

Pfizer entered into its distribution arrangement with Flynn because it wanted to avoid the negative publicity that would be associated with its pricing action. Pfizer had long provided the drug to the NHS system through its own distribution network. Following its agreement with Flynn, it would supply exactly the same drug from exactly the same factory, but using Flynn as an intermediary that was entitled to its own cut (or distribution margin). Flynn would be responsible for defending the new elevated pricing in the media and before regulatory authorities. Pfizer and its executives would, in theory, be insulated.

Phenytoin sodium capsules are an old-line treatment for epilepsy, and are no longer prescribed for new patients. However, the drug remains effective for patients who are taking it, which totals about 48,000 individuals in Britain. As the UK population ages and new patients are prescribed different treatments, demand for the AED is slowly declining. Important to the market definition aspect of the case – and the finding of abuse of dominance – is that there is risk associated with switching patients to any new formulation of the drug once they are stabilized on it, including switching between manufacturers of bioequivalent versions. In consequence, the Medicines and Healthcare Products Regulatory Agency in the UK advised strongly against switching formulations or manufacturers, and UK dispensing pharmacists largely followed that advice. This made it very difficult for third parties to enter the market with competing generics. Pfizer and Flynn were found to enjoy a dominant position on the UK market for phenytoin sodium capsules.

The decision of the CMA, reflecting its in-depth investigation, is detailed and lengthy, and the CAT decision is also long.[4] But, some of the key elements can nevertheless be laid out concisely. The CMA and CAT each took as the leading jurisprudence applicable to excessive pricing the 1978 decision of the Court of

[3] The evidence of meetings and Pfizer internal correspondence set out in the CMA decision included the following:

"[Company A] subsequently met Pfizer on 29 January 2010 and gave a presentation on its proposal. Following the meeting, [Pfizer's Head of EPBU] emailed colleagues, explaining that Pfizer needed to progress [Company A]'s Proposal as the 'potential upside is huge' and that Pfizer could not 'afford to dismiss this lightly'."

However, [Pfizer's Head of EPBU] had a number of unresolved questions. One of these was resolving the dilemma between convincing patients that nothing would change while at the same time explaining to "DH and payers" that things would change:

"Trust

3. We need to work out how we can position this as 'no change' with patients & physicians; and at the same time 'change' with DH and payers without being accused of hypocrisy by pursuing a trust agenda, yet **taking the opportunity to fleece the NHS in [a] time of funding crisis**." [emphasis added. Citations to document identification omitted], CMA Decision, at 3.221.

[4] The CMA decision is 550 pages, and the CAT decision 150 pages.

Justice of the European Union (CJEU) in the *United Brands* case.[5] That decision set out a two-step analytical framework for determining excessive pricing, under what is today Art. 102 of the Treaty on the Functioning of the European Union (TFEU) (abuse of dominant position).[6] First, the relevant authority determines whether the price charged by the accused is "excessive", with a determination of cost and selling price "which would disclose the amount of the profit margin" expressly set out as an acceptable benchmarking methodology. The second step of the inquiry is to assess whether the excessive price is "unfair", either "in itself or when compared to competing products". I have previously noted that this is a somewhat curious judicial formulation in that a price may be deemed excessive yet fair,[7] but this is the long-standing perspective of the CJEU.

The CMA established a "cost-plus" benchmark price for the AED, including direct and indirect costs, and a profit margin of 6%. Pfizer argued that continuing to sell phenytoin sodium capsules at the formerly controlled price was not profitable, or at least not sufficiently profitable within its portfolio. Although it might have obtained approval for a price increase from the British regulatory authorities, it considered that a regulatorily permissible price increase would not be adequate. The CMA accepted that some increase in the price of the product might be justified, but based on an extensive review of evidence found that Pfizer and Flynn together had grossly exceeded the boundaries of justifiable pricing. The CMA-adopted profit margin reflected that phenytoin sodium capsules are a long-established generic. Price increases by Pfizer and Flynn to the NHS were between 2300 and 2600% of pre-hike prices.[8]

Having found that the prices charged by Pfizer and Flynn were excessive in relation to its cost-plus determination of the benchmark, the CMA found that the prices were unfair in themselves because there was no reasonable relationship between the economic value of the products and the prices charged.[9] The CMA said that it was not appropriate to determine economic value on the basis that patients would suffer and health system costs would rise if the drug was unavailable, since the patients had no real choice as to whether to purchase the products, and because

[5] Case 27/76, *United Brands Co. & United Brands Cont'l B.V. v. Comm'n of the European Cmtys*., 1978 E.C.R. I-207. *See* discussion in Abbott (2016).

[6] *United Brands Co*., 1978 E.C.R. at 301, paras. 248–252.

[7] Abbott, at p. 296.

[8] Per the CMA's official press release at the time of decision:
"Since September 2012, Pfizer has continued to manufacture phenytoin sodium capsules and has supplied them to Flynn Pharma at prices that were significantly higher than those at which it previously sold Epanutin in the UK – between 780% and 1,600% higher than Pfizer's previous prices. Flynn Pharma then sells on the products to UK wholesalers and pharmacies charging them prices which have been between 2,300% and 2,600% higher than those they had previously paid for the drug."
CMA fines Pfizer and Flynn £90 million for drug price hike to NHS, CMA Press Release, 7 December 2016, https://www.gov.uk/government/news/cma-fines-pfizer-and-flynn-90-million-for-drug-price-hike-to-nhs.

[9] Per the CMA Decision: "The CMA considers that Pfizer's Prices and Flynn's Prices bear no reasonable relationship to the economic value of Pfizer's Products and Flynn's Products respectively and are each therefore unfair in themselves." (at 5.350).

Pfizer was not providing any additional value beyond that which had been provided before the price increase.[10] The CMA noted that having made a determination that the prices were "unfair in themselves" it did not need to make a determination as to whether the prices were also unfair when compared to competing products. However, for sake of completeness the CMA took note, for example, that Pfizer continued to provide the same drug profitably at much lower prices in other Member States of the EU.[11] It recognized that these Member States had different regulatory regimes, but noted that Pfizer and Flynn had not put forward any "objective dissimilarities", and said that the disparities in pricing were so large "it is unlikely there would be any 'objective dissimilarities' that could justify such differences".[12] It did not consider such a detailed analysis necessary in light of its finding that the prices were unfair in themselves.

The CMA also declined to use the price of a non-competitive product, phenytoin tablets, as a comparator in regard to excessive pricing or unfairness. Tablets were prescribed to a significantly smaller patient population than capsules, and the main provider, Teva, had been criticized by the NHS for its prices, even though the NHS had not formally taken action to lower the price (having achieved a substantial price reduction through informal objection).[13]

The CAT on appeal by Pfizer and Flynn upheld the CMA's determination of market dominance,[14] but rejected its findings on excessive pricing and unfairness, on grounds that the CMA should have given more consideration to the alternative arguments made by Pfizer and Flynn. One of its principal reasons was a subsequent decision by the CJEU in the *Latvian Copyright* case,[15] in which the CJEU had approved a methodology of determining excessive pricing and unfairness by comparison of prices charged in Latvia with those in two other Baltic states, and with PPP-adjusted prices with other Member States. In that case, a cost-price approach had not been followed by the relevant competition authorities because determining the cost of song-writing as part of a benchmark was problematic.

The decision of the CAT in the Pfizer/Flynn case was not based on the judgment of the CJEU. It was instead based on the opinion of Advocate General Wahl in that case.[16] Although the CJEU referred to several points of the AG's opinion approvingly in its decision, it did not adopt the AG's proposed multiple methodology analytic process.[17] The CAT appeared to understand, or at least consider, that the opinion of the Advocate General did not carry the weight of the

[10] *Id*., at 5.529–5.530.

[11] *Id*., at 5.450.

[12] *Id*., at 5.525.

[13] *Id*., *e.g.*, at 7.26.

[14] CAT Decision, at para. 253.

[15] *Autortiesību un komunicēšanās konsultāciju alģentūraaģentūra/Latvijas Autoru apvienība v. Konkurences padome*, CJEU, Case C-177/16, 14 September 2017. *See* this issue of IIC at https://doi.org/10.1007/s40319-018-0735-x.

[16] Opinion of Advocate General Wahl, Case C 177/16, 6 April 2017 (hereinafter "AG Wahl Opinion"). *See* CAT Decision, *e.g.*, at paras. 292–293.

[17] The CAT acknowledges that the decision of the CJEU was on narrower grounds than AG Wahl's expansive Opinion, but says this was [a]s would be expected. CAT Decision, at 295.

CJEU, but it "found AG Wahl's Opinion to be very persuasive and helpful in the present case and [we] regard his overall analysis as eminently sensible."[18] This point merits emphasis because the CAT rejected the excessive pricing decision of the CMA on the basis of the Advocate General's Opinion, and *not* on the basis of the CJEU's decision.

In its *Latvian Copyright* judgment, the CJEU restated its prior approval of the cost-price approach to determinations of excessive pricing, but accepted (as in some earlier jurisprudence) that cost-price was not always practicable and that alternative methodologies can be used.[19] In the *Latvian Copyright* case, reference to third country prices as a benchmark was practicable, and acceptable. In addition, on the "unfairness" limb it was acceptable to look toward prices in comparable third-country Member States. The decision was most notable in that the CJEU said that there was no minimum threshold for price differentials that would manifest "unfairness", and that the matter needed to be evaluated on a case-by-case basis.[20] The CJEU's judgment in the *Latvian Copyright* case did not appear to change in any material way the CJEU's prior jurisprudence on excessive pricing, except to the extent it may have relaxed the standards for finding unfairness by refusing to articulate a low-end threshold for determinations of unfairness in the context of cross-market comparisons.

The AG's Opinion reflected a strong reticence toward excessive pricing as a competition law doctrine,[21] though acknowledging that it is expressly provided for in Art. 102 of the TFEU, and further acknowledging that excessive pricing is possible in markets affected by regulation of one form or another.[22] The AG put forward the Chicago School's view that markets correct themselves, and that excessive pricing is not possible in competitive markets. He cited Justice Scalia's

[18] *Id*., at para. 307.

[19] The CJEU said:

"36 In that regard, the questions to be determined are whether the difference between the cost actually incurred and the price actually charged is excessive, and, if the answer to that question is in the affirmative, whether a price has been imposed which is either unfair in itself or unfair when compared with competing products (judgment of 14 February 1978, United Brands and United Brands Continentaal v Commission, 27/76, EU:C:1978:22, paragraph 252).

37 Nonetheless, as observed in essence by the Advocate General in point 36 of his Opinion, and as the Court has also recognised (see, to that effect, judgment of 14 February 1978, United Brands and United Brands Continentaal v Commission, 27/76, EU:C:1978:22, paragraph 253), there are other methods by which it can be determined whether a price may be excessive."

[20] The CJEU said:

"55 … There is in fact no minimum threshold above which a rate must be regarded as 'appreciably higher', given that the circumstances specific to each case are decisive in that regard. Thus, a difference between rates may be qualified as 'appreciable' if it is both significant and persistent on the facts, with respect, in particular, to the market in question, this being a matter for the referring court to verify."

[21] He said: "Nevertheless, in its practice, the Commission has been extremely reluctant to make use of that provision against (allegedly) high prices practiced by dominant undertakings. Rightly so, in my view. In particular, there is simply no need to apply that provision in a free and competitive market: with no barriers to entry, high prices should normally attract new entrants. The market would accordingly self-correct." AG Wahl Opinion, at para. 3.

[22] *Id*., para. 4.

observation from the *Trinko* decision that high prices are a reward for innovation, and that they encourage market entry by third parties.[23] But, the AG Opinion acknowledges that markets are not always competitive and self-correcting, notably when subject to government regulation.

The AG's skeptical view toward excessive pricing doctrine is reflected in his view that multiple methods should be employed in assessing the same pricing behavior.[24] Thus, for example, he suggests that even if a cost-price methodology has been used by the competition authority, that same authority should also perform a competitive product analysis to confirm the assessment. He cautions against incomplete analysis, saying that this might work to the detriment of the undertaking being investigated.[25] The general thrust of the AG Opinion is that the competition authority must be vigilant in protecting the interests of the accused undertaking, and the AG strongly cautions against competition authorities acting as price regulators.[26]

The CJEU has made clear that under the "unfairness" prong of its two-step analytic framework a price may either be unfair in itself, or unfair in comparison to competing products. These are not cumulative conditions. The competition authority may demonstrate either one. However, the AG does not appear to agree with that.[27] He refers to using a competing product comparison in addition to a cost-price comparison as a "sanity-check".[28]

As noted earlier, the CJEU judgment in the *Latvian Copyright* case does not incorporate the "multiple methodology" requirement suggested in the AG Opinion. But, the UK Competition Appeal Tribunal rejects the decision of the CMA – despite its detailed assessment of markets, costs and prices – because it might have tried out more methodologies as suggested by the AG, even though the judgment of the CJEU does not establish such requirement.

The CAT acknowledged the detailed assessment that the CMA performed with respect to cost-plus, but said that it had improperly excluded alternative methodolo-

[23] *Id*., para. 117.

[24] The AG Wahl Opinion says, *e.g.*, "it is in my view crucial that in order to avoid (or, more correctly, to minimise) the risk of errors, competition authorities should strive to examine a case by combining several methods among those which are accepted by standard economic thinking and which appear suitable and available in the specific situation." *Id.*, para. 43.

[25] *Id.*, para. 53.

[26] The AG Wahl Opinion says:

"… a strict approach would require competition authorities essentially to become price regulators which ought continuously to monitor and intervene in (potentially all) regulated markets. Clearly, unlike sectoral authorities, competition authorities have neither the resources nor the expertise to do that. Moreover, the loss of consumer welfare may at times be minor and not justify a complex, time-consuming and costly intervention by the public authorities…" *Id.* at para. 105.

[27] The AG's perspective is encapsulated in the following:

"In conclusion, it is only when no rational economic explanation – other than the mere capacity and willingness to use market power even when abusive – can be found for the high price applied by a dominant undertaking that that price may be qualified as abusive under Article 102 TFEU." (AG Wahl Opinion, at para. 131)

[28] *Id.*, para. 124.

gies.[29] It also faulted the CMA for establishing a benchmark price in what it described as "idealised competition", rather than the "real world".[30] Notwithstanding that the CJEU decision in *United Brands* clearly sets out that a cost/price comparison is an acceptable basis for establishing excess, the CAT relies on the AG Opinion to say that this is not enough.[31] It finds fault with the CMA as follows:

> It has on the whole avoided making comparisons with other products or companies and made little significant attempt, other than by invoking the Price Comparison over Time, to place Pfizer's and Flynn's prices in their commercial context during the Relevant Period.[32]

Regarding excess, the CAT concludes:

> In Pfizer's case, we consider the CMA's theoretical approach may understate what the appropriate benchmark price for Pfizer would notionally have been under conditions of normal and sufficiently effective competition, but without further investigation we are not in a position to say whether this is the case.[33]

While it is true that *United Brands* neither suggests nor implies that cost-price is the sole methodology for determining excess, it clearly states that "This excess could, *inter alia*, be determined objectively if it were possible for it to be calculated by making a comparison between the selling price of the product in question and its cost of production, which would disclose the amount of the profit margin…". The *United Brands* decision does not say that an alternative methodology must or should also be employed. This is something that the CAT derives from the AG Opinion.

Regarding unfairness, the CAT again faulted the CMA because of its reliance on one of the two approaches to determining unfairness established by the CJEU, notwithstanding its acknowledgment that the two tests are not cumulative.[34] A demonstration of unfairness under one of the two approaches is sufficient.[35]

[29] CAT Decision, at 310.

[30] *Id.*

[31] It says:
"… in our judgment, United Brands does not establish that Cost Plus is, in isolation, a sufficient method for establishing the excess if other methods are available and, particularly, if they suggest different results. Moreover, it is clear that an authority cannot simply choose that method of calculating the excess that was most favourable to establishing an infringement, to the exclusion of other methods. United Brands provides no support for such a proposition and nor would it accord with AG Wahl's Opinion. Such an approach would run the risk of being unfair to the party alleged to have infringed and of being insufficiently robust." *Id.* at para. 314.

[32] *Id.* at para. 318.

[33] *Id.* at para. 357.

[34] The CAT says:
"For the reasons given below, we find that the CMA has not correctly assessed whether the prices it found to be excessive under the Excessive Limb were also unfair within the meaning of Article 102 TFEU. It wrongly relied only on Alternative 1 (unfair in itself) in assessing unfairness under the Unfair Limb and therefore did not properly assess the possible impact of meaningful comparators (in particular, phenytoin tablets) for the purpose of assessing whether the prices charged were unfair." Id. at para. 362.

[35] The CAT further says:
"That is not to say that the authority cannot find that there is an infringement where one Alternative demonstrates unfairness and the other does not since it does not need to succeed on both heads. However,

In determining unfairness in itself, the CMA examined the extraordinary price increases adopted by Pfizer and Flynn with a demonstrated intent to use their dominant market position involving a captive NHS and patients to extract excessive prices, while providing no increased benefit or change of any kind. The CAT faulted the CMA for not sufficiently taking account of Teva's high prices for non-substitutable tablets, implying that excessive pricing by a generic pharmaceutical provider is acceptable if another generic firm is managing to extract high prices.

It is important to bear in mind that the CMA noted that Pfizer profitably charged much lower prices for its phenytoin sodium capsules in other EU markets, and that Pfizer had not provided any objective explanation for the differential between the UK and other markets. In that sense, the CMA had used the approach approved by the CJEU in the *Latvian Copyright* judgment, in which the CJEU further said that there was no minimum differential in price that was required to find unfairness. That said, the CAT said that the CMA should have further explored potential regulatory differences that might have caused Pfizer to sell its products throughout the EU at lower prices than the UK, notwithstanding that Pfizer had not made a demonstration on that element.[36] The CAT merely added another approach that the CMA might have used in its already exhaustive analysis in the face of Pfizer and Flynn's pricing scheme that the CAT acknowledged involved very large price increases on their face.

The CMA had rejected the position of Pfizer and Flynn that the economic value of phenytoin sodium capsules supplied by them should have included a supplement based on the value of treatment to the patients. The CMA said that the price increases did not reflect any change in circumstance. After the "debranding", patients received exactly the same product made in exactly the same factory, but at much higher prices. While it did not seem to have a good idea about why there should be some added economic value, the CAT nevertheless said:

> In light of the above, our finding is that the Decision was defective in its treatment of the economic value that may be derived from patient benefit. Placing a precise monetary value on patient benefit is not straightforward but it appears to us that a qualitative assessment would be possible and should have been attempted by the CMA rather than simply assessing this value as nil.

Human well-being is not a corporate asset for which rent should be recalculated to suit shareholder profitability expectations.

The "net" is that the CAT, in reliance on the opinion of Advocate General Wahl – which was rendered after the CMA decision – rejected the CMA determination of excessive pricing on grounds that the CMA could have looked at even more indicia

Footnote 35 continued
the authority must consider whether a prima facie case of fairness under one Alternative undermines the basis for the finding of unfairness under the other Alternative and produce a reasoned basis for determining that the Unfair Limb is satisfied.

This is necessary not only as a matter of logic but also in order to accord with the burden of proof and respect the presumption of innocence. It also accords with the approach in AG Wahl's Opinion that Alternative 2 of Limb 2 functions as a 'sanity check'." *Id.* at paras. 367–368.

[36] *Id.* at para. 402.

of excessive pricing and unfairness, notwithstanding clear evidence of intent by Pfizer and Flynn to take unfair advantage of the NHS and its patients by imposing massive price increases when they enjoyed a dominant position on the market. Pfizer knew what it was doing would trigger public outrage, and it engaged Flynn to take the heat.

The CJEU in the *Latvian Copyright* judgment affirmed its *United Brands* judgment, and if anything made it easier to prosecute an excessive pricing case by making clear there is no minimum threshold of price differentials between markets for assessing excess and unfairness. The CAT appears to have taken away from that judgment that it should make it more difficult to prosecute an excessive pricing case even in the face of egregiously bad conduct.

The British Parliament has legislatively closed the loophole that permitted Pfizer to circumvent price controls through its debranding exercise. But, that fact does not reduce the importance of penalizing Pfizer and Flynn for abusing dominant position through excessive pricing to the detriment of the UK public.

The CAT requested additional briefing on the question of remanding the decision, though it is not entirely clear what it was seeking with that. Presumably the options for the CMA were to reopen the investigation and pursue further evidence and analysis, or to appeal the CAT decision. Each course of action could have merit. There is little doubt that on further investigation the CMA would again find Pfizer and Flynn to have engaged in excessive pricing. The potential downside of that approach was that acceptance of the misguided CAT jurisprudence would burden investigators going forward. A successful appeal will clear the jurisprudential air by limiting excessive pricing investigatory requirements to those articulated by the CJEU. An appeal might also include a referral by the appeals court to the CJEU. (Of course, Brexit may play a role since the jurisprudence of the CJEU might cease to be directly relevant for the UK.) Indeed, on June 28, 2018, the CMA reported that it has sought permission from the CAT to appeal its decision to the Court of Appeal.[37] It was not inconceivable that the CMA would decide that it had enough, and that it lacked the resources to reengage with Pfizer and its lawyers. That would have been an unfortunate result for UK public policy and for competition jurisprudence more generally.

Reference

Abbott FM (2016) Excessive pharmaceutical prices and competition law: doctrinal development to protect public health. UC Irvine Law Review 6(3):281–320

[37] Report available at: https://www.gov.uk/cma-cases/investigation-into-the-supply-of-pharmaceutical-products.