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The Aspen Italy decision: A "quick look" assessment leaves open questions

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Skadden Arps Slate Meagher & Flom partner Ingrid Vandenborre and associate Stanislas de Villoutreys advise Aspen Pharmacare in relation to the ongoing proceeding of the European Commission that excludes Italy. In their commentary, they consider that the Aspen decision of Italy's Competition Authority, upheld by the Regional Administrative Tribunal of Lazio's judgment, has skipped the unfairness analysis set out by European Court of Justice in United Brands*. The commentary is based on the Aspen decision and judgment as published.*

On 29 September 2016, Italy's Competition Authority issued a decision against Aspen Pharmacare finding that the company had engaged in excessive and unfair pricing in relation to four oncology products. The Regional Administrative Tribunal of Lazio upheld the

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authority's decision in the first instance, but following Aspen's appeal, the tribunal's judgment is now under review by the Council of State.

The decision, as confirmed by the judgment, is interesting for multiple reasons. It is one of the very few decisions finding an excessive pricing infringement in relation to pharmaceuticals, where price levels are already regulated by EU member state pricing authorities. Particularly because of the latter aspect, the case raises questions as to the scope of permissible price negotiations and increases for medicines.

The leading European Court of Justice judgment, in *United Brands* from 1978, holds that a price is unfair where "it has no reasonable relation to the economic value of the product supplied." The legal analysis involves: first, determining whether the difference between costs actually incurred and the price actually charged is excessive (cost-price analysis); and if so, second, determining whether the price is unfair in itself or when compared to competing products.

The authority's decision and the tribunal's judgment present a much more abbreviated analysis, centered on the size of the price increases and the uniqueness of the products, and concludes that the price increases were unjustified and unfair on the basis that there was not sufficient evidence that costs had increased at the time of the request.

In this respect, the Italian decision takes an approach similar to that of the UK's Competition and Markets Authority that found in December 2016 that the prices applied by Pfizer and Flynn for phenytoin were excessive and unfair. The CMA determined that it was unnecessary to prove their unfairness through a comparison with the prices of comparable products, and relied essentially on a cost-plus approach to the exclusion of other methodologies.

The case law of the European Court of Justice has taught us that a finding of excessive pricing requires not only an assessment of the price cost relationships, but that that assessment should be undertaken using different parameters, and be supplemented with a consideration of other factors such as the economic value of a product, the market circumstances and business strategies relating to the products concerned and their pricing, as well as the price levels of competing products.

The key points of the Italian decision

First, the decision noted that while Aspen purchased the four oncology products from their originator, GlaxoSmithKline, in 2009, the products were developed in the 1950s and 1960s. The decision noted that for most of the products, the original prices had been in force without any increase since their first entry into trade more than 40 years ago.

Second, the decision also found that their patent protection had expired years earlier, and that no generics had entered since the patent expiration or were likely to do so. It also concluded that no therapeutic substitutes existed, identifying only products based on the same molecule and for the same categories of patients as relevant to its analysis.

Third, the decision assessed the products' prices, both before and after the increase, against their costs pursuant to the first part of the *United Brands* test. Relying on estimates of the company's direct and overhead costs and taking into account Aspen's investment in purchasing the portfolio, the decision concluded that the historic prices were profitable. However, relying upon data of costs actually incurred, Aspen submitted that the historic prices resulted in limited and negative margins.

Fourth, the decision remarked that the request for a price increase in 2013 had been based exclusively on the need for Aspen to align the Italian prices with the prices in other European countries and stated that Aspen did not document an increase in production or distribution costs, nor justify the increase by innovative efforts, research and development or other improving factors. These, per the decision, constituted the sole grounds that could justify a price increase.

Fifth, the decision concluded that there were no relevant comparators to assess the products' prices. There were no other products based on the same molecule and for the same categories of patients, except in different geographic markets which were not considered comparable.

Last, the decision found that Aspen had unfairly negotiated with the Italian price regulator, as Aspen had indicated that it would withdraw the products from direct sales in Italy and supply the products through imports if the price increase requested was not accepted, given the difference in the price levels with the other member states and the resulting parallel exports causing supply difficulties.

Price cost analysis and beyond

In comparison with other excessive pricing decisions and judgments, it is noteworthy that the decision presents an abbreviated assessment that essentially skips the second part of the *United Brands* test.

The decision's analysis is fundamentally affected by the notion that there are no alternatives for the products; and the assumption that the price elasticity of demand for each product is zero. This affects both the finding of dominance, and the application of the *United Brands* test.

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The decision defines the relevant market at the level of the individual molecule for treatment of specific patient groups based on a number of expert opinions and concludes Aspen's dominance on that basis. There appears to be no basis to assume however – particularly in the context of an excessive pricing analysis – that the sales of off-patent originators are only constrained by generics of the same molecule, rather than, for example, a generics foreclosure analysis. The European Commission in its substitutability assessment of oncology products for market definition purposes in the Sanofi-Synthélabo/Aventis and Novartis/GSK mergers looked at oncology guidelines to identify alternative treatments.

Even if the relevant market could be defined on that basis, the assumption that the products are unique seems to have immediately ruled out any proper unfairness assessment. The European Commission and European Court of Justice advocate general Nils Wahl have indicated in the past excessive pricing cases of *Scandlines v Port of Helsingborg* and AKKA/LAA that the reference to "competing products" for the purpose of assessing unfairness under *United Brands* does not only mean products competing in the same market as the product under investigation; it also includes "(i) other prices charged by the dominant company on a market different from the relevant market or (ii) prices charged by other firms providing similar products/services on other relevant markets."

This is also echoed in the judgment of the UK Competition Appeal Tribunal correcting the CMA's assessment against Flynn and Pfizer, finding that the authority should have considered in more depth the suitability of comparators, including those of other pharmaceuticals not in the same product market. The Italian decision's exclusion of any relevant comparators, including in different geographic markets for example, effectively avoids any analysis under the second part of the *United Brands* test.

Although the Italian Aspen decision does assess whether the difference between the costs incurred and the prices charged is excessive, it conducts a very limited analysis of cost.

First, for purposes of its assessment the decision allocates indirect costs first in proportion to direct costs and then also in proportion to 2013 revenues. Neither method seems wholly acceptable. If businesses could not charge more than an equal share of indirect costs on any product, they would not be viable. All businesses have some products that are more profitable than others.

The decision also relies on other assumptions. For example, Italy's Competition Authority assumed a value for the investment that Aspen had made in purchasing the products, as a multiple of GSK's profit from marketing them, and assumed that Aspen would be able to recover that investment cost over 20 years – even though the authority's own entry analysis appears to require entrants to break even in only three years. It also assumes that revenue would simply increase in proportion to price on the basis of a price elasticity of zero; that is,

that Aspen would not lose any sales to competitors. It finds that the decrease in sales after the price increases is likely attributable to the reduction in parallel exports.

These all seem to be very specific assumptions, and the analysis raises questions as to how companies can price products within this framework where indirect costs should be allocated in equal measure to each product, and investments can be expected to break even only after 20 years. The recent Latvian case of societies that manage royalty rights for authors has been helpful in confirming the applicable standards. In AKKA/LAA, European Court of Justice advocate general Nils Wahl expressed the concern that in addition to being accurate, the methodology applied by the competition authority should also be "sufficient": "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."

In addition to a price cost analysis, a finding of excessive pricing must be based on a conclusion that the gap between price and cost is unfair, either in itself or in comparison to competing products. This is the second part of the *United Brands* test. As indicated above, however, there was no comparison of prices to those of products used for similar therapeutic indications in Italy or elsewhere in the decision, as the decision excluded the existence of comparators on the basis that they did not belong to the products' product or geographic markets. It would have been interesting, for example, to look at the prices of the products' competitors in other European countries – particularly given that that was the purpose of Aspen's requested price increase – as well as prices of drugs used for the same indications. The importance of comparing prices across products and geographies has been the approach generally identified, including by the European Court of Justice in its recent judgment in the *AKKA/LAA* case; by the European Commission in the recent *Gazprom* decision; and by the UK Competition Appeal Tribunal in *Phenytoin*.

Having concluded that no comparators for the products exist, the Italian authority reduced the *United Brands* test to a comparison of the products' current prices to those prior to the increase. Moreover, neither the decision nor the judgment upholding it provides an assessment as to why the historic prices constituted a valid benchmark. Both the European courts and the UK tribunal require a review whether the historic prices are prices that "would hypothetically have [been] charged had there been effective competition in the market."

For example, an assessment of market developments and other changes in supply and demand-side factors have been considered important in this context. Surely with prices that have not been revised since the products were launched several decades ago, as stated several times in the decision, one would have to take that factor into account in assessment of the historic price levels. Italy's Competition Authority did note that prices had not been

updated for decades but did not draw the conclusion that prices thus must have been well below normal competitive levels bearing in mind compounded inflation over 40 years and increased regulatory standards.

The decision also reflects a very limited analysis of entry, which is surprising especially as the products had been off-patent for a long time. The decision concluded that entrants could not be profitable at the increased prices – even though the historic prices were deemed profitable for Aspen – because it considered that an entrant would have to incur all the regulatory costs involved in entering Italy, and would have to recover those costs in a three-year period.

This is a surprising analysis for a few reasons. First, there are regulatory procedures to make it easier and cheaper to enter multiple European Economic Area countries, or to enter one when already present in another, which is what most companies do. It is unclear why entry should be assumed to take place only in Italy. Second, the decision's analysis of cost recovery within a three-year period clearly misinterprets the cited European Commission merger guidelines. The three-year period is relevant to assess whether a company can be treated as a potential competitor based on the likelihood that it will, within that time period, undertake the necessary additional investments or other necessary switching costs to enter the relevant market. Having entered, the time to recover costs is likely to be considerably longer, possibly 20 years – as the decision itself assumed for amortising Aspen's investment cost. The decision did not assess price levels as a factor disincentivising entry, even though the commission's pharmaceutical sector inquiry has identified the price of the originator drug as a relevant factor.

The decision noted that the price increases resulted in a decrease in Aspen’s product sales, but simply attributed that to a decrease in parallel exports of the products. Interestingly, the struggle with product supply in the face of parallel exports had been the main reason the company requested that prices in Italy be increased to bring them in line with products elsewhere in the EEA. The decision does not address the legitimacy of this approach, even after having identified the products as unique, and indispensable to patients in Italy.

It is also interesting to consider the weight attached by Italy’s Competition Authority to the products' economic value. The *United Brands* test seeks to evaluate whether the price of a product or a service bears a reasonable relation with its economic value, but the Aspen decision only briefly assessed the economic value of the products. The authority noted that, in the absence of a legal definition, the economic value of the products "has to reflect at least a measure of the production costs incurred by the company to create the good or the service provided". It then stated that other factors, such as qualitative improvements of the products or the related service, could be included in the economic value. The authority did not focus on the economic value of the products, but on the potential improvements of the products' quality: it noted that the increase in price did not correspond to an increase in

value and concluded that the economic value was therefore correctly approximated by the totality of direct and indirect costs identified in the previous section.

Of course, this is a significant limitation on the concept of economic value applied by the EU courts and the European Commission. Having identified the products as important to certain patients and taking into account the supply issues that were identified by the company triggered by parallel exports as a result of widely diverging price levels in the EEA, the circumstances of the price increase would have merited further consideration.

Finally, the decision also finds that Aspen engaged in abusive negotiations, as the company had indicated that if the requested price increase were not accepted, Aspen would withdraw the products from direct sales in Italy and supply them through imports to deal with depletion of supplies from Italy to other member states. The decision raises key questions in relation to the scope of negotiating power for pharmaceutical companies. The commission in the *Glaxo* decision in 2001 specified that "pharmaceutical companies have negotiating power when discussing prices for domestic sales," and "the possibilities of obtaining price increases are not theoretical", concluding that "the [pricing] authorities leave room for real price bargaining and do not set the prices unilaterally". The commission indicated that "it is too simplistic to refer to conflicting national price regulations as unilateral state measures" imposed on pharmaceutical companies "since these companies have negotiating power vis-à-vis the national authorities" that set maximum prices.

The Aspen decision casts doubt on the scope for negotiation that pharmaceutical companies really have, however, and what would exactly entail an abuse in the circumstances of a negotiation. It also reopens the question of whether there can be dominance on the part of pharmaceutical companies at all, if their power over pricing is less significant than in other industries. It is a factor that Advocate General Wahl also referenced as relevant in assessing excessive pricing allegations in *AKKA/LAA*. In *GlaxoSmithKline*, the General Court observed in 2006 that "in effect, even on the assumption that the Spanish regulations confer a power of negotiation on the pharmaceutical companies, as the Commission and the interveners again maintained at the hearing, the fact remains that the existence of those regulations, and their coexistence with the regulations of other member states, has a significant impact on an essential parameter of competition, a contextual element which cannot be overlooked in the competitive analysis." This also seems a highly relevant consideration in relation to the Aspen decision.

In sum, the decision of Italy's Competition Authority fining Aspen on the basis of alleged excessive pricing, and the judgment confirming it, leave questions unanswered. Very much like the CMA when it found Pfizer's and Flynn's prices to be unfair, the Italian decision's analysis is based solely on a price cost analysis, and comparison with historic prices that date back decades. It will be interesting to see how the Council of State will analyse the applicable test.

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