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No Patient or Illness to be Treated? The Hazards of Investigations Carried Out Under Article 102 TFEU for Price-Related Conduct (The Netherlands, Case 7069, *AstraZeneca*)

Hans Vedder*

I. Introduction

The pharmaceutical sector has always featured prominently in EU law, with myriad parallel trading and patent exhaustion cases to start with. More recently, however, competition law plays an increasingly important role in the interface between the practices in this sector and the internal market acquis. Recent high-profile cases, for example, are the *GlaxoSmithKline* judgments concerning differentiated pricing,¹ and the *AstraZeneca* judgments on misleading information for supplementary protection certificates.² In addition to the European cases, many national proceedings have been initiated, such as the *Napp* case in the UK³ and the decision of the Authority for Consumers and Markets (ACM or the Authority) in the *AstraZeneca* case in the Netherlands.

That decision⁴ is interesting for three essential reasons. Firstly, it sets out exhaustively the type of information and evidence that are required to find restrictive effects arising from the abuse. Secondly, it shows how theories of harm are developed by competition authorities using better understanding of the sector involved. Finally, the decision features an elaborate reasoning only to come to the conclusion that *AstraZeneca* is not dominant and that there is no reason for action.

II. The Case

As many Western European countries, the Netherlands faces increasing costs of healthcare and attempts to reduce these costs. One of the ways in which it attempted to reduce these costs is by actively encouraging the use of generics over patented substances. This means that

Key Points

- When starting investigations on price-related practices under Article 102 cases, authorities should know that it may be difficult to bring the case to a successful end by establishing the existence of an abuse and of a dominant position.
- The lesson was recently learnt by the Dutch Competition Authority in a case involving *AstraZeneca*—a pharmaceutical company charging hospitals in the Netherlands prices considerably lower than the ones charged on the non-hospital, general pharmacy market as part of a strategy for leveraging sales achieved in the former to the latter market.
- In that case, no infringement of Article 102 TFEU could be found despite far-reaching investigations as *AstraZeneca* did not have a dominant position.

whenever a doctor prescribes a specific brand, like Nexium, the pharmacist has to provide that branded medicine. When a doctor prescribes only an active substance, like esomeprazole, the pharmacist is incentivised by the healthcare insurance companies to substitute the branded drug with a generic drug. This 'preference policy' is coordinated by the healthcare insurance companies and means that essentially only the costs for the cheapest drug for a certain active substance and those that cost no more than 5 per cent more than the cheapest drug are reimbursed.⁵ This means that as soon as gener-

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1 Case T-168/01 *GlaxoSmithKline Services Unlimited v Commission*, ECLI:EU:T:2006:265 and Joined Cases C-501/06 P, C-513/06 P, C-515/06 P, and C-519/06 P *GlaxoSmithKline Services Unlimited v Commission*, ECLI:EU:C:2009:610.

2 Cases T-312/05 *AstraZeneca v Commission*, ECLI:EU:T:2010:266 and C-457/10P *AstraZeneca v Commission*, ECLI:EU:C:2012:770.

3 Documents are available at: <<http://www.catribunal.org.uk/237-565/1001-1-1-01-Napp-Pharmaceutical-Holdings-Limited-and-Subsidiaries.html>> accessed 6 August 2015.

4 Decision of 24 September 2014 of the ACM in Case 7069, *AstraZeneca*, available from acm.nl, hereafter the *AstraZeneca* decision, para. 10.

5 *AstraZeneca* decision, paras 129–133.

ics are marketed, there will be a downward price effect, unless the doctor prescribes a specific brand of drug. Doctors are encouraged to prescribe on the basis of active substance rather than brand name.

To further refine this, and to understand the case, it is important to know that this preference policy only applies to general pharmacies. As a result, general pharmacies that provide the drugs prescribed by non-hospital doctors are equally under pressure to substitute branded drugs with generics. For hospital pharmacies, the drive to reduce costs also comes from the healthcare insurance companies, but in a slightly different form. In a nutshell, hospitals receive their budget from the healthcare insurance companies on the basis of a projected number of medical interventions they undertake in a year. Such 'diagnosis and treatment combinations' may include the treatment with [proton pump inhibitors (PPIs), a pharmaceutical substance designed to deal with gastric acid such as AstraZeneca's Nexium]. If such treatment includes a PPI, the incentive for the hospital is to prescribe the cheapest PPI, as this would leave more of the budget per diagnosis and treatment combination. In a nutshell, hospitals are price-sensitive drugs buyers, and essentially the competition takes place where the manufacturer tries to get on the list of drugs that can be prescribed by doctors in that hospital, the 'formularium'.⁶ However, most of the drugs prescribed in a hospital will need to be taken by the patient after he is released from hospital, and this is where the case becomes interesting.

Basically, the ACM found evidence for and worked on the basis of the theory that pharmaceutical companies know that once a branded drug has been prescribed by a hospital doctor, general practitioners (GPs) will continue to prescribe this branded medicine. As such, substitution by generics and prescriptions on the basis of active substances only takes place minimally. This is referred to as the 'radiation effect' that basically holds that turnover on the hospital market can be leveraged to the general pharmacy market.⁷ To substantiate this radiation effect, the ACM presents several public sources, like the office for fair trading's *Napp* decision and statements by the Minister for Health Care and the Association of Health Care Insurance companies.⁸ It also mentions several documents from AstraZeneca that mention a radiation effect, endorsement effect, or

follow-on effect.⁹ Interestingly, this section of the decision ends without a finding by the ACM itself, but rather the statement that various sources acknowledge the existence of such an effect.¹⁰

This endorsement effect is quantified on the basis of hospital sales and a comparison with sales by general pharmacies, leading to the conclusion that 11–12 per cent of Nexium sales by general pharmacies can be attributed to hospital prescriptions.¹¹ The ACM, subsequently, qualifies this as 'substantial' by the ACM. AstraZeneca, however, contends that there is no causal connection between hospital sales and sales by general pharmacies, that the data are not representative, and that the effect is not significant enough to warrant the conclusions taken by the ACM. The interesting point that can be taken from this discussion relates to the temporary nature of the radiation effect, with AstraZeneca stating that patients will switch away from Nexium after a few prescriptions following their release from the hospital. The ACM agrees with this and comes to the conclusion that the effect will only last a short time in most cases.¹²

III. Prices Charged by the Company

The next section of the decision studies the development of turnover for PPIs in the Netherlands. It shows a steady increase in output and significant discounts for branded drugs in hospitals.¹³ Price decreases for PPIs in the general pharmacy market are attributed to the several interventions that took place, such as the preference policy.¹⁴ The interesting part of this section is the interim conclusion that the data show such a radiation effect for all producers of branded drugs, an interim finding that precludes the final conclusion that AstraZeneca's dominance could not be proven.¹⁵

The ACM then determines the prices for the hospital market in an absolute sense as well as in relation to the avoidable costs. This shows very significant discounts, in the 90–100 per cent bracket, and finds that variable costs are not covered by these prices.¹⁶ Further to the radiation effect, the ACM finds that prices of Nexium in general pharmacies are 66–90 times those charged in hospital pharmacies. On average, the price on the general market is 81 times higher than the price on the hospital market.¹⁷ This price differential is then explained. The ACM essen-

6 *AstraZeneca* decision, paras 121–123.

7 This coincides largely with the follow-on effect and/or endorsement effect also mentioned in the decision.

8 *AstraZeneca* decision, paras 144–157.

9 *AstraZeneca* decision, paras 158 and 159.

10 *AstraZeneca* decision, para. 160.

11 *AstraZeneca* decision, para. 170.

12 *AstraZeneca* decision, para. 178.

13 *AstraZeneca* decision, paras 181–189.

14 *AstraZeneca* decision, paras 190–193.

15 *AstraZeneca* decision, para. 202.

16 *AstraZeneca* decision, paras 212–225.

17 *AstraZeneca* decision, para. 235.

tially refers to the radiation effect,¹⁸ whereas AstraZeneca points to the fierce competition between Nexium and the market leading PPI Pantozol.¹⁹

Again, this signals the ultimate outcome of this case. In this regard, the ACM finds that it is ‘not inconceivable’ that AstraZeneca used loss-leading prices to ensure that it would be prescribed as much as possible. It further states that it has no reason to believe that AstraZeneca was engaged in a conscious strategy to limit the sale of generics on the hospital or general market. As to the fierce competition with Pantozol, the ACM simply states that AstraZeneca’s strategy still was profitable.²⁰ This profitability is attributed to the radiation effect and exists even when this effect would have been very small.

Following this discussion of the market at hand, the ACM moves to the legal appraisal. As with all dominance cases, the market is first defined. In this regard, the ACM finds a geographical market limited to the Netherlands and a product market that encompasses all PPIs, but needs to be differentiated between the hospital and general markets. On the hospital market for PPIs, Pantozol is the market leader, whereas Nexium has a market share below 30 per cent, leading to the finding that AstraZeneca did not have a dominant position.²¹ The ACM will, therefore, not apply Article 102 TFEU and the equivalent provision in the Netherlands Competition Act. Given that the case is about leveraging from the hospital market to the general market, only the market share in the former matters. The market share in the general market is not investigated.

IV. Theories of Harm

The *AstraZeneca* decision fits in a line of cases that started with a number of energy-related cases. This is so because the refined analysis of the actions of the companies on the market is better understood following a sector inquiry and using the insights from the partners in the European Competition Network (ECN). Concerning energy, the sector inquiry triggered a number of Commission interventions that essentially followed up on information that would hardly be intelligible, even for a well-informed outsider such as a competition au-

thority. The limited use of certain power plants in the middle of the merit order to raise wholesale prices is a practice that requires significant understanding of the electricity market to be detected, let alone qualifies as something harmful to competition.²² In this regard, the careful analysis of prices for the various forms in which Nexium would be distributed and administered in the various markets as well as the related costs shows this detailed understanding of the market. The same holds for the analysis of the market at hand in the light of pharmaceutical effectiveness. Moreover, the exchange of information in the ECN has further enabled enforcement. In this case, the *Napp* decision first mentioned the radiation effect on the basis of which hospital sales would trigger follow-on sales in the general pharmacy market, excluding generics.²³

This radiation effect also points to the theory of harm underlying this case. This appears to work on the hospital market functioning as a gate to the general market,²⁴ with predatory prices on the hospital market²⁵ limiting access for generics to and (possibly) recoupment on the general market. This is hardly a simple theory for this intervention. Indeed, reading the case, one may wonder why this was followed up by the Authority in the first place, given that competition authorities are so keen to demonstrate their outcome.²⁶ I wonder what the outcome of this would have been if AstraZeneca had engaged in the same conduct and had been found dominant. To answer this question, we need to take a closer look at the radiation effect.

At the end of the day, the radiation effect starts with out-of-hospital prescriptions being insufficiently influenced by price considerations. Or, put differently, it turns on non-hospital doctors insufficiently contemplating whether cheaper generics would have the same therapeutic effectiveness as the branded drug that was prescribed by the hospital doctor. This is a factor that is only indirectly connected to the originator company’s actions. Indeed, the ACM highlights that the Association of GPs, the out-of-hospital doctors that will issue most follow-on prescriptions, has actually instructed its members to be more keen on substituting branded drugs with generics.²⁷ More specifically and relevant to the theory of harm underlying this case, the Association of GPs has

18 *AstraZeneca* decision, paras 236–249.

19 *AstraZeneca* decision, para. 251.

20 *AstraZeneca* decision, para. 257.

21 *AstraZeneca* decision, paras 282 and 283.

22 This was found in Case COMP/39.388, German Electricity Wholesale Market.

23 *AstraZeneca* decision, para. 13, mentions that information had been asked from the British and Swedish competition authorities.

24 *AstraZeneca* decision, para. 143 and notably Footnote 147 and para. 202.

25 That is prices below (identified) variable costs, *AstraZeneca* decision, para. 225.

26 For the Authority see: <<https://www.acm.nl/nl/publicaties/publicatie/12714/Outcome-ACM-2013/>> accessed 6 August 2015.

27 *AstraZeneca* decision, para. 154.

pointed out that the GPs will refer patients that have been prescribed expensive branded drugs back to the hospital doctors, forcing the latter to consider prescribing cheaper generics. This effectively back-pedals on the radiation effect, making the hospital doctors more aware of the price effects of their prescription decisions within the hospital.

Why, we may ask, would the GPs not substitute the drugs themselves? The ACM notes in this regard that many of the GPs are reluctant to prescribe a generic drug in view of what they perceive to be the superior knowledge of the specialist hospital doctors as well as the patients' desire to keep with the drug prescribed.²⁸ In this regard, we note that the sector inquiry has highlighted that originator pharmaceutical companies are engaged in marketing campaigns designed to induce such consumer loyalty, suggesting that non-branded medicine is somehow less trustworthy.²⁹ Such findings only complicate the radiation effect, as it appears to be the result of the hospital price in combination with the induction of loyalty in the out-of-hospital market. Basically, both factors have little if anything to do with the unique position that a dominant undertaking finds itself in. Most, if not all, companies will engage in some form of cross-subsidisation at some time and marketing products, also in relation to competing products, is an equally normal phenomenon. In a nutshell, there appears to be no particular reason to bring the business practices in the case at hand within the scope of the *Michelin* special responsibility. For the company under investigation, this is confirmed by the market analysis that reveals one of its competitors as market leader.

All in all, the radiation effect cannot be traced back to a simple and well-articulated theory of harm, which in turn brings us back to the question why it was pursued in the first place. This question becomes all the more pressing, particularly in view of the market share of the company under investigation. There must have been early indications that AstraZeneca's market share would not support a finding of dominance, so why was public money spent in this way? At this point, we can only

speculate. The political and societal pressures to reduce healthcare costs may have triggered the ACM to at least show that it is doing what it can do. This is impossible to verify. It could also be understood as an attempt to create awareness of the radiation effect among the doctors/pharmacists involved so as to offer them 'preventive guidance'. In a way the decision reads as a show of force, with the Authority flexing its muscles and showing what it could have done.³⁰

V. Conclusion

Finally, this case really makes me wonder about the (more)(economic) effects-based approach to Article 102 TFEU.³¹ Is this an example of the ACM erring on the side of caution in the absence of (economic) effects? Not really, as the ACM never mentions an actual exclusionary effect or the absence of it. The only measured effects mentioned in the decision are the price difference between the hospital and out-of-hospital market³² and the price below average variable costs in the hospital market.³³ Of these two findings, only the latter can constitute an abuse in line with generally accepted economics and the Court's case law. Following on from Areeda and Turner, prices below average variable costs are said to be irrational, unless they are part of a plan to exclude competition after which the losses will be recouped.³⁴ In this case, however, the below-cost prices in the hospital market seem perfectly rational. Even in the absence of cut-throat competition on that market, can a company really be blamed for wanting to get its product noticed by selling it a very low price and then recouping this loss in follow-on sales? This, to my mind, is a widely accepted business practice. In this regard, the submission by the ACM to the United Nations Conference on Trade and Development roundtable on pharmaceutical markets may shed some light on the reasons or undertaking anti-trust action nonetheless.³⁵ One of the members of the ACM board there mentioned that they had investigated the high drug prices in the Netherlands and found essen-

28 *AstraZeneca* decision, para. 140.

29 Pharmaceutical sector inquiry, staff working paper part 1, paras 951–955, available at: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf> accessed 6 August 2015.

30 This, however, would be odd. For one, the sector involved, and particularly the hospital doctors and GPs that are the linking pin in the radiation effect, is aware of the effect as the ACM itself abundantly shows in the decision. The increased awareness of such an effect has triggered GPs to refer patients with branded drugs back to the specialist so that the latter could consider prescribing a cheaper generic. This may trigger such specialist doctors to automatically prescribe a generic to a patient leaving the hospital or at least inform the patient that his or her GP will prescribe the equally effective generic once the drugs prescribed in the hospital run out.

31 The debate on this topic is not always held with analytical clarity. For a critical appraisal, see WPJ Wils, 'The judgment of the EU General Court in

Intel and the so-called "more economic approach" to abuse of dominance' <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2498407> accessed 6 August 2015, pp. 8–10.

32 *AstraZeneca* decision, para. 235.

33 *AstraZeneca* decision, para. 225.

34 See, however, HJ Hovenkamp, 'Predatory pricing under the Areeda-Turner test' (U Iowa Legal Studies Research Paper No. 15-06) <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2422120> accessed 6 August 2015, who notes at p. 6 that the AVC test is particularly ill-suited in situations with high fixed costs, such as—incidentally—the pharmaceutical market.

35 Speaking points are available from: <<https://www.acm.nl/nl/publicaties/publicatie/14483/Speech-Anita-Vegter-UNCTAD-8-juli-2015-Pharmaceutical-markets-and-consumers/>> accessed 6 August 2015.

tially two reasons: the reimbursement system and the way doctors prescribe drugs. Both have very little—if anything at all—to do with the pharmaceutical companies. Indeed, under the heading of advocacy, the ACM suggests that other methods than competition law may be more apt to lower drug prices. So, if we understand the AstraZeneca decision in the light of advocacy as regards the healthcare insurance companies, the health-

care legislator, and medical doctors, it makes some sense. As regards the pharmaceutical companies that are the subject of antitrust actions, it seems to me that the ACM had the syringe filled up and the pills ready with a glass of water. Only then to realise that there was no patient that could be treated . . .

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