Reference: 7069/1832
Case number: 7069
Date: 24 September 2014

1 SUMMARY

1. On December 23, 2011, the Netherlands Competition Authority (hereafter: NMa) sent AstraZeneca a Statement of Objections informing it about the suspicion that, in the period of 2002 through 2010, the undertaking allegedly abused a dominant position with respect to the drug Nexium. At various points in the procedure that followed, AstraZeneca gave its opinion about the investigation launched by the NMa, and it challenged the provisional conclusions that the NMa had drawn.

2. In this decision, the Netherlands Authority for Consumers and Markets (hereafter: ACM)[1] comes to the final conclusion that *it has not been established* that AstraZeneca violated Section 24 of the Dutch Competition Act (hereafter: Mw). In addition, ACM sees *no grounds for action* in the context of its power to apply Article 102 of the Treaty on the Functioning of the European Union (hereafter: TFEU).

3. The case this decision relates to is about the Dutch market for PPIs, i.e. medicines for the treatment of heartburn, gastroesophageal reflux disease, and gastric ulcers[2]. The range of available PPIs in the period in question consisted of several brand-name (or branded) drugs protected by patents such as Nexium, and 'brandless,' generic drugs (for example omeprazol), which contain active ingredients[3] that are no longer protected by patents.

4. With regard to the *facts* of this case, ACM first of all assessed the functioning of the market. When buying drugs, hospitals (or health care institutions in general) look at the therapeutic effectiveness of the drugs. Because of budget restrictions, they are also price-sensitive. AstraZeneca responded to that situation, and often supplied Nexium to hospital pharmacies at a substantial discount. The price of Nexium, when supplied to community pharmacies, for use outside of hospitals, was considerably higher. This relatively high price must be reimbursed to patients by health insurers if Nexium (or actually, the active ingredient therein) is prescribed by physicians. Current regulations do not allow pharmacies to substitute with generic drugs. If a certain branded drug is prescribed by medical specialists in hospitals, such prescriptions have spillover or "follow-on" effects on the prescriptions by physicians, including general practitioners (GPs),

[1] On April 1, 2013, the Establishment Act of the Netherlands Authority for Consumers and Markets came into force. Since that day, the Netherlands Authority for Consumers and Markets (hereafter: ACM) has been the legal successor of the Netherlands Consumer Authority, the Netherlands Competition Authority (hereafter: NMa) and the Netherlands Independent Post and Telecommunications Authority. ACM has since exercised the powers of each of its three legal predecessors.

[2] Technically speaking, it concerns drugs that function as *proton pump inhibitors (PPI)*.

[3] The active ingredient is the chemical substance or component in the drug that is therapeutically active.

outside of the hospitals, in the sense that it increases the likelihood that the same branded drug is also prescribed by those physicians. ACM finds it plausible that Nexium's spillover effect was significant. This means that it could have been a lucrative proposition for AstraZeneca to increase sales to hospitals by supplying at below cost price, as the losses incurred in the hospital market could be recouped sufficiently in the community market. This strategy led to a situation where the hospital market for generic drugs was commercially less attractive, as manufacturers of generic drugs were not able to similarly benefit from any spillover effect.

5. The investigation into the facts looked into the substitution options between the different PPIs. AstraZeneca has challenged, supported with reasons, the provisional conclusion in the Statement of Objections regarding the virtually full therapeutic interchangeability of the different PPIs. Based on the file, it cannot be established with certainty to what extent any therapeutic interchangeability between Nexium and other (generic) PPIs exists, which means that, at least to that extent, the Statement of Objections requires nuancing. This is taken into account by ACM in its legal assessment of Nexium's position on the market.

6. One final element of the investigation into the facts, which was also a topic of discussion in this case, concerned the possible effects of Nexium's low pricing for hospitals on the community market. In general, when generic drugs are introduced, savings in drug use costs are expected, and, by extension, in health care costs, too. The investigation has revealed that, in the relevant period, the sales of generic omeprazol lagged behind its trend-based projected growth. ACM considers it justified to assume that the sluggish growth of generic PPIs on the community market had a negative effect on the moderating effect that the introduction of generic PPIs normally could have had on health care costs. In the decision phase, however, ACM took into account that the sluggish growth of generic omeprazol could have had different causes, which cannot be separated based on the file. Besides Nexium's prices, the therapeutic qualities of the drug, for example, could have played a role, as could have the development of other patented PPIs such as Pantozol. ACM therefore refrains from giving an opinion about the extent to which various factors could have contributed to a 'more expensive' drug use.

7. In the *legal assessment*, ACM first of all faced the question of whether AstraZeneca, with regard to Nexium, enjoyed a dominant position on any market within the meaning of Section 24 Mw and Article 102 TFEU. This was not the case in the hospital market. Yet, in the Statement of Objections, a separate community market had been identified, consisting of users who, due to the spillover effect, were bound to Nexium. The arguments that AstraZeneca put forward regarding, among other aspects, substitution, therapeutic effectiveness and switching behavior of PPI users, have raised reasonable doubts about the conclusion that a group of Nexium users was bound to Nexium through the spillover effect to such an extent and on such a scale that, with regard to this group, AstraZeneca was able to behave independently of its competitors within the meaning of

Section 24 Mw and Article 102 TFEU. Taking everything into consideration, ACM comes to the conclusion that, based on the facts at hand, it cannot be sufficiently established that AstraZeneca enjoyed a dominant position on a separate relevant market as defined in the Statement of Objections. The possibility that Nexium enjoyed a dominant position in a different segment of the extramural market was not part of ACM's investigation, which means that no conclusion can be drawn about that.

8. As it has not been established that, with regard to the drug Nexium, AstraZeneca enjoyed a dominant position in any relevant market in the relevant period, AstraZeneca can thus not be accused of abuse thereof within the meaning of Section 24 Mw and Article 102 TFEU. The question of whether the described pricing behavior could result in abuse within the meaning of national and European prohibitions in circumstances different from those of the case at hand is therefore not up for discussion in this decision.

9. Following the above, ACM comes to the final conclusion that AstraZeneca cannot be imposed any sanction.