Recent Commission Merger Control Decisions in the Pharmaceutical Sector: Sanofi-Aventis/Zentiva and Teva/Barr

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1. Introduction

On 5 September and 3 November 2008, respectively, the Commission received two notifications of proposed mergers involving generic drug companies. The first concerned the plan for Sanofi-Aventis, a French innovator drug company, to acquire control of Zentiva, a regional generic player in Central and Eastern Europe particularly strong in the Czech Republic, Slovakia and Romania (‘SA/Z’). The second involved two generic companies, with Teva of Israel acquiring control of US-based Barr (‘T/B’).

These two cases raised a number of new issues, which are reflected in the corresponding decisions. Both transactions were cleared in phase one with commitments, but in reverse order of notification following an incompleteness decision on SA/Z: T/B was decided on 19 December 2008 and SA/Z on 4 February 2009.

2. Market Definitions

Both cases display a number of grey areas in the market definition compared with the reference framework of ATC3 classes used in earlier decisions, although the ATC3 approach was maintained as a starting point (7). In both cases, the Commission looked at narrower possible market definitions, which included analysis of potentially problematic markets at ATC4 and molecule level and, in some cases, between different galenic forms (8). These grey areas are the result, in particular, of overlaps in genericised markets, as in Teva/Barr both companies were generic companies, whilst in Sanofi-Aventis/Zentiva the target was a company active only in the field of generics.

In line with previous decisions, the Commission considered it appropriate to carry out analyses at levels other than ATC3 also, or at a mixture of levels, if the circumstances of the case show that the undertakings involved face sufficiently strong competitive constraints at another level and there are indications that the ATC3 class does not lead to a correct market definition.

In certain instances, in both decisions the Commission considered that the relevant market could be narrower than ATC3 and might be at ATC4 (9) or molecule level (5). In particular, the relevant market was found to be the molecule for the oncology products involved in T/B. This was based on the market investigation which had indicated that, on genericised markets, competition might primarily be between drugs based on the same molecule, especially in the case of drugs against serious illnesses purchased by hospitals. In those cases, in particular if hospitals procure pharmaceuticals by means of competitive tenders, they are limited to drugs based on the same molecule.

In other instances, however, the molecule was explicitly excluded as the relevant market when it could be established that drugs based on other molecules were indeed substitutable, both in SA/Z (for certain beta-blockers, osteoporosis drugs and antihistamines) and in T/B (inter alia for tranquilisers) (10). There are also examples where the relevant market was established, or at least considered, based on a subset of more than one, but not all, of the ATC4 classes belonging to a given ATC3 class (sedatives were to exclude barbiturates and antidepressants to exclude herbal products and products indicated exclusively for bipolar disorder) (6).

In a number of other instances the Commission left the exact product market definition open, while nonetheless taking into account the closeness of substitution due to overlaps at either molecule or ATC4 level, both as one criterion contributing to the conclusion that serious doubts existed and also, in cases where there was no such overlap, to exclude such doubts (8).

The Commission also systematically looked at the distinction between OTC and prescription mar-

(1) The content of this article does not necessarily reflect the official position of the European Communities. Responsibility for the information and views expressed lies entirely with the authors.
(2) T/B paragraphs 10-11; SA/Z paragraphs 12-20.
(3) SA/Z paragraphs 121-130.
(4) SA/Z paragraphs 102 (though this was finally left open) and paragraph 129 (also left open).
(5) T/B paragraphs 34, 42, 49, 84 et al. It should, however, be noted that this approach was already partly prefigured for oncology in COMP/M.3354 Sanofi-Synthelabo/Aventis; cf T/B paragraph 28.
(6) SA/Z paragraphs 109, 140-144, 174; T/B paragraphs 116, 158, 164.
(7) SA/Z paragraphs 164-165; T/B paragraphs 162-164.
(8) For the ATC4 level as indicative of closeness of substitution, see, inter alia, SA/Z paragraph 223 and a contrario paragraph 246; for the molecule level see SA/Z paragraphs 454, 461, 469 and a contrario SA/Z paragraph 396.
markets (9) and frequently relied on this distinction (10), but nonetheless left open the possibility that this distinction might not always lead to separate relevant markets (11). In some instances the Commission also took into account specific characteristics of hospital use and demand (12) and, where relevant, analysed the hospital segment separately (13). Finally, the SA/Z merger raised the possibility that, as is implicit in the definition of relevant product market (14), price may sometimes be a relevant indicator to consider for market definition purposes in pharmaceutical cases, particularly for drugs whose prices differ greatly. However, price by itself is not conclusive (15).

In SA/Z, two further points are noteworthy in connection with market definition.

The first relates to active pharmaceutical ingredients (APIs), where the Commission concluded that the ingredient (molecule) may not always be the relevant market if it can be substituted by other inputs for the same class of medicines, at least where it takes a limited overall share of comparable inputs used in this class (16). This was the case for ethylmorphine, a substitutable input in antitussive preparations.

The second is the discussion of contract manufacturing, where the Commission concluded that the relevant geographic market was likely to be at least EEA-wide, but left open the extent to which specific technologies might create separate relevant product markets (17). Whilst horizontal concerns in the upstream (manufacturing) market were easy to exclude, the Commission also looked at instances where the merging parties manufactured on behalf of a competitor in the same downstream market too, in order to assess whether the market share may be partly accretive, in that this competitor might be less independent of the parties than other competitors and thus unable to compete as aggressively. However, no instances were identified where this consideration altered the analysis.

Filter system to focus the market investigation

In its merger decisions in the pharmaceutical sector, the Commission has previously relied on a filter system to focus the market investigation, given the frequently large number of product and geographic market combinations in which overlaps occur. The number of such markets was probably even larger in these two cases than on previous occasions.

Since Novartis/Hexal(18), the Commission has been using a classification with three groups. This classification was used in the T/B and SA/Z cases too, where Group 1 products are those with a combined market share of over 35% post-merger and an increment of over 1%, Group 2 products those with an increment in market share of less than 1% and Group 3 products those with a combined market share of below 35%. However, T/B in particular — in which molecule-level overlaps were a particular issue — explicitly required this filter to be passed at both ATC3 and molecule level (19). This was likewise the case in SA/Z at ATC4 and molecule level (20). The OTC/prescription distinction was also considered in both cases wherever relevant (21).

The purpose of this classification is to focus the investigation on those markets where issues are most likely to arise. It therefore does not preclude that issues may be identified in other areas. In SA/Z there are a number of instances where market definitions are discussed in areas which initially passed these filters, but based on uncertain market definitions. This is not necessarily limited to alternatives consisting of a single ATC4 class or of a single molecule. Where the Commission was able to exclude certain possible market definitions, as a result of which the filter criteria were then passed, serious doubts could be excluded in respect of such markets without discussing them individually in the decision (22).

In SA/Z the Group 2 classification proved to require particular scrutiny in instances where a low market share reflected Zentiva’s very recent entry into a category previously dominated by patent drugs, including those of Sanofi-Aventis (23). In such instances, it needed to be verified whether this might significantly underestimate the probable market share in the near future. Even if gains by Zentiva might be partly or wholly at the expense of Sanofi-Aventis in such cases — as a result of generic substitution — the potential loss of the Zentiva product following the merger could have had an effect on prices. In all the instances examined, however, such concerns could be excluded.

As in previous cases, the Commission based its assessment on sales value data from IMS. In addition (24). T/B paragraphs 12-13; SA/Z paragraphs 21-24.
(17) SA/Z paragraphs 51-54, 58.
(18) T/B paragraph 17; SA/Z paragraph 80.
(19) SA/Z paragraph 80, paragraphs 292-294, paragraphs 297-299.
(20) Section 6(l) of form CO in Annex 1 to the Implementing Regulation.
(21) SA/Z paragraphs 81, 95.
(22) SA/Z paragraphs 81-185.
(23) SA/Z paragraphs 187-192.

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to sales value, the Commission also considered, where the specifics of a market in SA/Z made it relevant, market shares based on ‘days of treatment’. This allowed comparison of actual use of drugs with different molecules and/or prices (26).

3. Potential Competition

In SA/Z the Commission had to consider potential competition in two ways. In some instances, there was the issue of a number of planned generic entries by the target into markets where the acquiring innovator had molecules with ongoing or recently expired patent protection. Such competition would very probably materialise in the near term. Secondly, there was the more general issue of whether generic competition itself would be damaged by the transaction, resulting in the innovator’s molecules becoming less exposed to such competition. The question was, in particular, whether Zentiva, as a former incumbent national pharmaceutical company in the Czech Republic and Slovakia, might be in a unique position to compete with generic products on its home markets.

Both these causes for concern could be excluded, the first based on a product-by-product analysis and the second based both on the results of an econometric study and on evidence gathered during a field visit (27).

4. Competition problems identified

In T/B the Commission finally identified serious doubts on seventeen markets in Central and Eastern Europe. All but two of these were molecule-level markets in the oncology field. The other two were vitamin markets in Poland and also defined at molecule level.

In SA/Z the Commission identified fifteen markets raising serious doubts in a range of different therapeutic areas, including gastroenterology, cardiovascular, pain and sedatives. With the exception of the exclusion of barbiturates from the sedative market, which made a material difference only in Bulgaria and Romania, all these markets raised serious doubts at ATC3 level, sometimes restricting the market definition to prescription drugs only.

5. Remedies

In both decisions the Commission took a close look at its past remedy practice on pharmaceutical mergers to see whether this approach was still appropriate and was fully applicable to the cases at hand.

In previous decisions the Commission has accepted, as remedies, divestment of medicines limited to the country where the competition concerns actually arise, together with their brand names, marketing authorisations and all relevant know-how, but in most cases without specific staff and manufacturing or distribution assets. The medicines can still be marketed by the parties in question in countries where no concerns are raised and, as a result, end up being marketed by different companies in different countries. This approach has been considered justified because (i) most assets are not earmarked for the businesses concerned, and qualified purchasers will often have their own assets and not require, or wish to acquire, additional assets from the seller and (ii) for many established medicines there are few cross-border spillovers at brand level.

This remained the basic approach in both cases (28), but the Commission carefully assessed whether additional safeguards were needed in order to preserve the viability of such divestitures. In this respect, the Commission went further than in many past cases, in particular on two points: the commitments include an option on sales staff for most of the products (27) and they provide for stricter purchaser criteria, in order to ensure that the purchaser(s) will be able to compete effectively even without any transfer of production facilities.

Given that no dedicated production capacity was to be transferred, there was a need for transitional supply agreements until the purchaser could move production to its own sites. In this context, an appropriate transitional period was needed in order to strike the right balance between the incentive for the purchaser to transfer production and quickly become independent of the divesting party and the need to re-register production and avoid interruption of supply. In the market investigation the Commission observed that manufacturing relationships often continued long after products had been divested in earlier merger control proceedings. In both cases the Commission considered a period of three years appropriate on the basis of the market investigations (29).

The Commission also included provisions to facilitate relocation of production, including reasonable cost-plus pricing for technical assistance and production, no minimum batch sizes during the transitional period and all necessary assistance from the seller to transfer production, including cooperation

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(26) SA/Z paragraph 82.
(27) SA/Z, paragraphs 542-552.
(28) SA/Z paragraph 556; T/B paragraph 207.
(29) T/B paragraph 209 and Commitment 4(f); SA/Z paragraph 556 and Commitments 5(g) and (h).
(29) S/A paragraph 557 and Commitment 5(f); T/B paragraph 209 and Commitment 4(g).
on the regulatory side (29). In addition, in SA/Z the ability of the seller to relocate production was specifically included as one of the purchaser criteria in order to avoid a long-term supply dependence which would weaken the incentive to compete aggressively with the divested products (30).

SA/Z raised the related question of whether small batch sizes for individual countries, or use of multi-country labelling, might mean that a divested product for a small country would have insufficient scale and hence could only be produced at increased cost, thereby undermining the efficiencies to be restored by the remedy. Although the answer to this question was no for the products to be divested in that case, this will still have to be checked case by case in the future.

Finally, these cases raised the question of how best to group the products to be divested in order to divest a viable package without running the risk of certain products being purchased but then not aggressively marketed by the purchaser. In T/B, as most of the products to be divested were in the field of oncology and on a group of geographically close markets, it was in the interest of the viability of the package to require that these products should be transferred to a single purchaser, which must be active in the oncology field in the EEA (31). This solution also took into account that specific expertise is required in the field of oncology in order to be able to compete effectively. Given that the divestitures in S/Z were not focused on any particular therapeutical area, the Commission’s market test indicated that this matter should, in this case, not be pre-determined in the commitments since no single approach could be imposed ex ante without a risk that certain products might be purchased but then not aggressively marketed by the purchaser. However, in SA/Z too certain groupings were required in the interest of viability. These were (i) a right of first refusal for companies buying the same drug in another geographical area and (ii) that where several drugs were divested within a single (ATC3) market, they should all be sold to the same purchaser.

From the remedy point of view, SA/Z also raised the more general question of whether Zentiva, as a former ‘incumbent’, might be so specific that the competitive constraint which it exercised could not be reproduced by others, thereby rendering any divested product less effective as a competitive constraint. In principle, this might have been due to a number of factors, including consumer preferences, corporate brand, distribution advantages, economies of scale and scope, and regulatory preference. The Commission was able to exclude this hypothesis, however, based both on the evidence gathered during the site visit and on the market test of the remedies (32).

6. Conclusions

The pharmaceutical industry is currently going through a phase of significant consolidation, with a number of other deals reportedly being considered or already announced. Simultaneously, the issue of generic competition has been amply investigated in the Commission’s antitrust sector inquiry and a number of concerns were raised in the interim report (see article about the sector inquiry in this newsletter). The Teva/Barr and Sanofi-Aventis/Zentiva merger decisions are further key developments in the Commission’s thinking on competition in the pharmaceutical sector, in particular as regards generics, and will be important for future work in this sector. At the same time, the two cases also highlighted that the specifics of different pharmaceutical merger scenarios and product markets may have an impact on the focus and approach of the assessment.