Sanofi-Aventis/Zentiva
(Commission of the European Communities, Case No COMP/M.5253, February 2009)

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Summary

In early 2009, the Commission of the European Communities (hereinafter "the Commission")[1] cleared the proposed acquisition of the generic drug maker Zentiva N.V. (hereinafter "Zentiva") by Sanofi-Aventis Europe (hereinafter "Sanofi-Aventis"), subject to conditions. In light of Sanofi-Aventis' commitment to divest fifteen drugs in Eastern Europe, the Commission concluded that the proposed acquisition would not harm competition in the internal market.

The facts

In September 2008, the Commission received a notification of a proposed concentration involving an originator and a generic producer.[2] The concentration related to the acquisition of Zentiva, a generic manufacturer active in the Central and Eastern Europe, by Sanofi-Aventis, a global pharmaceutical group engaged in research, development, manufacture and marketing of healthcare products. The Commission had to decide whether to prohibit the operation or, on the contrary, to declare it compatible with the European Union (EU) internal market and authorize it.

The legal issues

In assessing the competitive effects of the proposed transaction between Sanofi-Aventis and Zentiva, the Commission first defined the relevant markets. While the Commission usually determines the product markets by referring to the third level of the anatomical therapeutic chemical (ATC) classification system, known by the abbreviation ATC3[3], it considered that the ATC4 level[4] or the active pharmaceutical ingredient (i.e. at the molecule level) – two narrower market definitions – could be more appropriate in the present case "given that generic pharmaceutical companies typically produce copies of originator drugs which therefore can normally be viewed as the closest substitute to those drugs".[5] According to the Commission, the molecule level should in particular be taken into account when:

> "i.) doctors may, or are even required to, prescribe medicines using the international non-proprietary name (INN) of the molecule rather than by brand name

[1] The Commission of the European Communities is known today as the European Commission.
[2] A notification of a concentration pursuant Art. 4 of the Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings ("EU Merger Regulation").
[3] The Commission uses the ATC classification devised by the European Pharmaceutical Marketing Research Association ("EphMRA") and maintained by EphMRA and Intercontinental Medical Statistics ("IMS"). ATC3 covers pharmaceuticals that are grouped in terms of their specific therapeutic indications (i.e. their intended use).
[4] ATC4 is the most detailed level. It consists of products that are grouped according to therapeutic or more frequently pharmacological criteria such as molecule class, formulation or mode of action.
[5] See paragraph 17 of the decision.

(ii.) reimbursement is based on the price of a generic version of the originator medicine and
(iii.) pharmacies may, or are required to, offer the patient the opportunity to substitute an originator medicine with a generic equivalent".[6]

From a geographic point of view, the relevant markets were defined as national in scope.

After defining the relevant markets, the Commission proceeded to the competition assessment of the proposed transaction. Interestingly, the Commission did not only base its analysis on the combined market shares in terms of value but also in terms of volume. Since generics are being sold at lower prices than original drugs, market shares based on value can significantly differ from market shares based on volume.

After investigating over 100 national pharmaceuticals markets, the Commission found that competition concerns could be excluded in the vast majority of these markets, in particular because Sanofi-Aventis and Zentiva had moderate combined market shares and a sufficient number of competitors would remain in these market following the transaction.[7] However, the Commission identified serious competition concerns on 15 markets relating to different therapeutic areas in the Czech Republic, Slovakia, Romania, Bulgaria, Hungary and Estonia. According to the Commission, the proposed transaction raised competition concerns due to the risk of reduced choice and/or price increase for hospitals, patients and the State treasury. As a result, the Commission concluded that the notified operation gave rise to serious doubts about its compatibility with the EU internal market.

In order to address the Commission's concerns, Sanofi-Aventis submitted commitments and offered to divest its business in the affected markets. The divestment businesses included, *inter alia*, all tangible and intangible assets, including intellectual property rights and all licenses permits and authorizations. On this basis, the Commission considered that the remedies submitted by Sanofi-Aventis were sufficient to remove all serious doubts raised by the concentration. The Commission therefore decided to clear the proposed transaction, declaring it compatible with the EU internal market.

Points of significance

- The *Sanofi-Aventis/Zentiva* case sets a good example of the Commission's approach to product market definition in the pharmaceutical industry. The Commission recognized that the ATC3 level is not always the most appropriate level for the purposes of market definition. In assessing competition between brand-name and generic drug producers, the Commission suggested the use of a narrower market definition, citing the ATC4 level and the active pharmaceutical ingredient (i.e. at the molecule).
- In *Sanofi-Aventis/Zentiva* and *Teva/Barr* (see the summary available in this database), the Commission considered that structural remedies, i.e. divestiture

[6] See paragraph 18 of the decision.
[7] European Commission, Press Release IP/09/210, 4 February 2009, Brussels, "Mergers: Commission clears Sanofi-Aventis' proposed acquisition of Zentiva, subject to conditions". Available at: https://ec.europa.eu/commission/presscorner/detail/en/IP_09_210.

measures, were sufficient to eliminate the serious doubts resulting from the proposed transaction.

Key words: Competition, EU merger control, acquisition, pharmaceutical merger, market definition, commitments.

Available at:
http://ec.europa.eu/competition/mergers/cases/decisions/m5253_20090204_20212_en.pdf