Furthermore, in the applicant's submission the marketing of medicinal products that are generics of the reference product Plavix could not be covered by the transitional period laid down in point 1.5 of Annex XII to the Act concerning the conditions of accession, because the exceptions provided for therein concerned exclusively the requirements of safety, quality and efficacy prescribed in Directive 2001/83/EC, and not the 10-year period of data protection laid down in Article 13(4) of Regulation (EEC) No 2309/93 and Articles 89 and 90 of Regulation (EC) No 726/2004.

- (¹) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).
 (²) Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down
- (2) Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ L 214, 24.8.1993, p. 1).
 (3) Regulation (EC) No 726/2004 of the European Parliament and of the
- (3) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

Appeal brought on 19 September 2008 by Knauf Gips KG against the judgment of the Court of First Instance (Third Chamber) delivered on 8 July 2008 in Case T-52/03 Knauf Gips KG v Commission of the European Commission

(Case C-407/08 P)

(2008/C 313/19)

Language of the case: German

Parties

Appellant: Knauf Gips KG (represented by: M. Klusmann and S. Thomas, Rechtsanwälte)

Other party to the proceedings: Commission of the European Communities

Form of order sought

 Set aside the judgment of the Court of First Instance (Third Chamber) of 8 July 2008 in Case T-52/03 Knauf Gips KG v Commission in its entirety;

- in the alternative, refer the case back to the Court of First Instance for a fresh decision;
- in the further alternative, reduce the fine imposed on the appellant by Article 3 of the contested Commission Decision of 27 November 2002 in an appropriate manner, and in any event by at least EUR 54,51 million;
- order the respondent to pay the costs of the proceedings.

Pleas in law and main arguments

The appeal against the judgment, by which the Court of First Instance dismissed the action brought by the appellant against Commission Decision 2005/471/EC of 27 November 2002, is based on three pleas in law.

- 1. By its first plea on appeal, the appellant submits that there was a breach of the rights of the defence, including a breach of the right to a fair hearing. The appellant submits that the Court of First Instance failed to observe the principles that apply with regard to the legal consequences of a refusal to grant access to incriminating documents and the withholding of exculpatory evidence. By the first part of this plea, the appellant submits that the Commission's decision should have been annulled, because the Commission denied the appellant access to incriminating evidence on which the decision was subsequently based. By the second part of the first plea, the appellant submits that the judgment under appeal involved a separate breach of the appellant's rights of defence, given that the Commission also illegally withheld exculpatory evidence, which likewise should have led to the annulment of the decision.
- 2. By its second plea on appeal, the appellant submits that there was an infringement of Article 81(1) EC, due to fundamental breaches of the rules on evidence, namely of the *in dubio pro reo* principle, as well as breaches of substantive law, namely as regards the elements constituting a concerted practice, which, in the judgment under appeal, led to the assumption constituting an error of law that Article 81(1) EC had been breached.
- 3. By its third plea on appeal, the appellant submits that there was an infringement of the 10 % ceiling under Article 15(2) of Regulation No 17/62. The appellant submits that the Court of First Instance wrongly attributed to the appellant the turnover of undertakings which the appellant does not control and which do not control the appellant. The appellant submits that it and those undertakings do not form part of the same economic unit.