V

(Announcements)

COURT PROCEEDINGS

COURT OF JUSTICE

Judgment of the Court (Fourth Chamber) of 24 January 2018 — European Commission v Italian Republic

(Case C-433/15) ([1])

(Failure of a Member State to fulfil obligations — Milk and milk products — Additional levy on milk — Tax years 1995/1996 to 2008/2009 — Regulation (EC) No 1234/2007 — Articles 79, 80 and 83 — Regulation (EC) No 595/2004 — Articles 15 and 17 — Infringement — Lack of effective payment of the levy within the time limits prescribed — Failure of recovery in the event of non-payment of the levy)

(2018/C 104/02)

Language of the case: Italian

Parties

Applicant: European Commission (represented by: P. Rossi, D. Nardi and J. Guillem Carrau, acting as Agents)

Defendant: Italian Republic (represented by: represented by G. Palmieri, acting as Agent, and by P. Gentili and S. Fiorentino, avvocati dello Stato)

Operative part of the judgment

The Court:

1. *By failing to ensure that the additional levy payable in respect of quantities produced in Italy in excess of the national quota, from the first year in which the additional levy was in fact applied in Italy (1995/1996) until the last year in which there was surplus production in Italy (2008/2009),*

   — *was in fact allocated to the individual producers which had contributed to each of the production overruns and*

   — *was paid at the appropriate time, upon their being given notification of the amount payable, by the purchasers or the producers in the case of direct sales, or*

   — *where the levy was not paid within the period prescribed, was registered and, where possible, recovered by way of enforcement from those purchasers or producers,*

   the Italian Republic has failed to fulfil the obligations imposed on it by Articles 1 and 2 of Council Regulation (EEC) No 3950/92 of 28 December 1992 establishing an additional levy in the milk and milk products sector, Article 4 of Council Regulation (EC) No 1788/2003 of 29 September 2003 establishing a levy in the milk and milk products sector, Articles 79, 80 and 83 of Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation), and, with regard to the Commission's implementing provisions, Article 7 of Commission Regulation (EEC) No 536/93 of 9 March 1993 laying down detailed rules on the application of the additional levy on milk and milk products, Article 11(1) and (2) of Commission Regulation (EC) No 1392/2001 of 9 July 2001 laying down detailed rules for applying Regulation No 3950/92, and, finally, Articles 15 and 17 of Regulation (EC) No 595/2004 of 30 March 2004 laying down detailed rules for applying Regulation No 1788/2003, as amended by Commission Regulation (EC) No 1468/2006 of 4 October 2006;

2. *Orders the Italian Republic to pay the costs.*

(1) OJ C 354, 26.10.2015.

Judgment of the Court (Grand Chamber) of 23 January 2018 (request for a preliminary ruling from the Consiglio di Stato) — F. Hoffmann-La Roche Ltd and Others v Autorità Garante della Concorrenza e del Mercato

(Case C-179/16) (1)

(Reference for a preliminary ruling — Competition — Article 101 TFEU — Agreements, decisions and concerted practices — Medicinal products — Directive 2001/83/EC — Regulation (EC) No 726/2004 — Allegations of risks associated with the use of a medicinal product for a treatment not covered by its marketing authorisation (off-label) — Definition of relevant market — Ancillary restriction — Restriction of competition by object — Exemption)

(2018/C 104/03)

Language of the case: Italian

Referring court

Consiglio di Stato

Parties to the main proceedings

Applicants: F. Hoffmann-La Roche Ltd, Roche SpA, Novartis AG, Novartis Farma SpA

Defendant: Autorità Garante della Concorrenza e del Mercato

Interveners in support of the defendant: Associazione Italiana delle Unità Dedicate Autonome Private di Day Surgery e dei Centri di Chirurgia Ambulatoriale (Aiudapds), Società Oftalmologica Italiana (SOI) — Associazione Medici Oculisti Italiani (AMOI), Regione Emilia-Romagna, Altroconsumo, Regione Lombardia, Coordinamento delle associazioni per la tutela dell'ambiente e dei diritti degli utenti e consumatori (Codacons), Agenzia Italiana del Farmaco (AIFA)

Operative part of the judgment

1. *Article 101 TFEU must be interpreted as meaning that, for the purposes of the application of that article, a national competition authority may include in the relevant market, in addition to the medicinal products authorised for the treatment of the diseases concerned, another medicinal product whose marketing authorisation does not cover that treatment but which is used for that purpose and is thus actually substitutable with the former. In order to determine whether such a relationship of substitutability exists, the competition authority must, in so far as conformity of the product at issue with the applicable provisions governing the manufacture or the marketing of that product has been examined by the competent authorities or courts, take account of the outcome of that examination by assessing any effects it may have on the structure of supply and demand.*

2. *Article 101(1) TFEU must be interpreted as meaning that an arrangement put in place between the parties to a licensing agreement regarding the exploitation of a medicinal product which, in order to reduce competitive pressure on the use of that product for the treatment of given diseases, is designed to restrict the conduct of third parties promoting the use of another medicinal product for the treatment of those diseases, does not fall outside the application of that provision on the ground that the arrangement is ancillary to that agreement.*

3. *Article 101(1) TFEU must be interpreted as meaning that an arrangement put in place between two undertakings marketing two competing products, which concerns the dissemination, in a context of scientific uncertainty, to the European Medicines Agency, healthcare professionals and the general public of misleading information relating to adverse reactions resulting from the use of one of those medicinal products for the treatment of diseases not covered by the marketing authorisation of that product, with a view to reducing the competitive pressure resulting from such use on the use of the other product, constitutes a restriction of competition 'by object' for the purposes of that provision.*