Judgment of the Court (Fourth Chamber) of 22 December 2010 — Commission v Poland

(Case C-385/08)

(Failure of a Member State to fulfil obligations — Accession of new Member States — Marketing authorisations for medicinal products that are generics of the reference product Plavix — Conditional decisions authorising the marketing of pharmaceutical products — Infringement of the acquis)

1. *Actions for failure to fulfil obligations — Subject-matter of the dispute (Art. 226 EC) (see paras 28-33)*

2. *Procedure — Application initiating proceedings — Formal requirements — Identification of the subject-matter of the dispute — Brief summary of the pleas in law on which the application is based — Unambiguous wording of the form of order sought by the applicant (Rules of Procedure of the Court of Justice, Art. 38(1)(c)) (see paras 34-37)*

3. *Approximation of laws — Medicinal products for human use — Marketing authorisation (Treaty of Accession 2003, Arts 2 and 24 and Annex XII, Chapter 1, para. 5; European Parliament and Council Regulation No 726/2004, Arts 89 and 90; Council Regulation No 2309/93, Art. 13(4); European Parliament and Council Directive 2001/83, Art. 6(1)) (see paras 62-70, 77-82, operative part)*

Re:

Failure of a Member State to fulfil obligations — Infringement of Article 6(1) of 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 2001 L 311, p. 67), read in conjunction with Article 13(4) of 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 1993 L 214, p. 1) and

with Articles 89 and 90 of 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 2004 L 136, p. 1) — Marketing authorisations for medicinal products that are generics of the reference product Plavix, in breach of the 10-year period of protection enjoyed by the latter — Conditional decisions authorising the marketing of pharmaceutical products, issued before the date of Poland's accession to the European Union but not becoming effective until after that date — Decisions inconsistent with the provisions of Directive 2001/83/EC.

Operative part

The Court:

1. Declares that,

— by retaining in force the decisions of the Minister for Health concerning marketing authorisations for medicinal products that are generics of the reference product Plavix, and

— by placing and keeping on the market, after 1 May 2004, medicinal products whose marketing authorisation was not issued in accordance with Article 6(1) of 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,

the Republic of Poland has failed to fulfil its obligations, as regards the first indent above, under Article 6(1) of Directive 2001/83, in conjunction with Article 13(4) of 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 and with Articles 89 and 90 of 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 and, as regards the second indent above, under Article 6(1) of Directive 2001/83;

2. Orders the Republic of Poland to pay the costs;

3. Orders the Republic of Lithuania to bear its own costs.

Judgment of the Court (First Chamber) of 22 December 2010 — Commission v Malta

(Case C-351/09)

(Failure of a Member State to fulfil obligations — Environment — Directive 2000/60/EC — Articles 8 and 15 — Status of inland surface water — Failure to establish monitoring programmes and make them operational — Failure to submit summary reports on those monitoring programmes)

Actions for failure to fulfil obligations — Examination of the merits by the Court — Situation to be taken into consideration — Situation on expiry of the period laid down in the reasoned opinion (Art. 226 EC; European Parliament and Council Directive 2000/60, Arts 8(1) and (2), and 15(2)) (see paras 26-28)

Re:

Failure of a Member State to fulfil obligations — Infringement of Articles 8 and 15 of Directive 2000/60/EC of the European Parliament and of the Council of 23 October establishing a framework for Community action in the field of water policy (OJ 2000 L 327, p. 1) — Obligation to establish and make operational programmes for the monitoring of the status of surface waters — Obligation to submit summary reports regarding the programmes for the monitoring of surface waters.