JUDGMENT OF THE COURT (Sixth Chamber)
14 March 1996 *

In Case C-239/95,

Commission of the European Communities, represented by Hendrik van Lier, Legal Adviser, acting as Agent, with an address for service in Luxembourg at the office of Carlos Gómez de la Cruz, of its Legal Service, Wagner Centre, Kirchberg,

applicant,

v

Kingdom of Belgium, represented by Jan Devadder, Director in the Ministry of Foreign Affairs, Foreign Trade and Cooperation with Developing Countries, acting as Agent, with an address for service in Luxembourg at the Belgian Embassy, 4 Rue des Girondins,

defendant,

APPLICATION for a declaration that, by failing to adopt and, in the alternative, to communicate to the Commission the measures necessary to transpose Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ 1990 L 189, p. 17), the Kingdom of Belgium has failed to fulfil its obligations under that directive and in particular Article 16 thereof,

* Language of the case: French.

THE COURT (Sixth Chamber),

composed of: C. N. Kakouris, President of the Chamber, G. Hirsch, G. F. Mancini, F. A. Schockweiler and J. L. Murray (Rapporteur), Judges,

Advocate General: D. Ruiz-Jarabo Colomer,
Registrar: R. Grass,

having regard to the report of the Judge-Rapporteur,

after hearing the Opinion of the Advocate General at the sitting on 15 February 1996,

gives the following

Judgment

1 By application lodged at the Court Registry on 6 July 1995, the Commission of the European Communities brought an action under Article 169 of the EC Treaty for a declaration that, by failing to adopt and, in the alternative, to communicate to the Commission the measures necessary to transpose Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ 1990 L 189, p. 17, hereinafter 'the Directive'), the Kingdom of Belgium has failed to fulfil its obligations under that directive and in particular Article 16 thereof.

2 Article 16 provides:

'1. Before 1 July 1992, Member States shall adopt and publish the laws, regulations and administrative provisions necessary in order to comply with this directive. They shall forthwith inform the Commission thereof.

They shall apply such provisions from 1 January 1993.

2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field covered by this directive.

...'

3 Since it had not received any notification of the national measures intended to implement the Directive nor had available any other information enabling it to conclude that the Kingdom of Belgium had transposed the Directive, the Commission gave the Belgian Government formal notice by letter of 14 October 1992 to submit its observations within two months.

4 Since it received no reply, the Commission sent a reasoned opinion to the Belgian Government on 2 July 1993, pursuant to Article 169 of the EEC Treaty, in which it reiterated the observations contained in the letter of formal notice. The Commission called upon the Belgian Government to adopt the requisite measures in order to comply with the reasoned opinion within two months of receipt of its notification.

5 No response to that reasoned opinion was received by the Commission within the prescribed period. However, by letter of 28 March 1995, the Belgian Government informed the Commission that a draft Royal Decree intended to transpose the Directive had been submitted for the opinion of the Conseil Supérieur d'Hygiène (Public Health Board).

6 Since it had not been informed of the results of that procedure, the Commission lodged the present application.

7 In its defence, the Belgian Government explains that the draft Royal Decree intended to transpose the Directive received a favourable opinion from the Conseil Supérieur d'Hygiène and the Inspecteur des Finances (Inspector of Taxes), but that the opinion of the Belgian Conseil d'État was still required.

8 It should be noted that on 1 July 1992, the date on which the time-limit for the transposition of the Directive expired, the Kingdom of Belgium had still not adopted any measures to implement it.

9 In those circumstances, it must be held that, by failing to adopt the laws, regulations and administrative provisions necessary to comply with the directive, the Kingdom of Belgium has failed to fulfil its obligations under Article 16 of that directive.

Costs

10 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs. Since the defendant has been unsuccessful, it must be ordered to pay the costs.

On those grounds,

THE COURT (Sixth Chamber)

hereby:

1. **Declares that, by failing to adopt the laws, regulations and administrative provisions necessary to comply with Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, the Kingdom of Belgium has failed to fulfil its obligations under Article 16 of that directive;**

2. **Orders the Kingdom of Belgium to pay the costs.**

Kakouris Hirsch Mancini

Schockweiler Murray

Delivered in open court in Luxembourg on 14 March 1996.

R. Grass C. N. Kakouris

Registrar President of the Sixth Chamber