OPINION OF ADVOCATE GENERAL RUIZ-JARABO COLOMER

delivered on 15 February 1996 *

1. In the present case, the Court of Justice is called upon to rule on the application made by the Commission on 6 July 1995 in which it seeks a declaration, pursuant to Article 169 of the EC Treaty, that by failing to adopt and bring into force within the prescribed time-limit the provisions necessary to implement Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, [1] and by failing to inform the Commission thereof, the Kingdom of Belgium has failed to fulfil its obligations under that directive.

2. As regards the time-limit for transposing Directive 90/385/EEC into national law, 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 received no information concerning the transposition of Directive 90/385/EEC within the prescribed period, the Commission considered that Belgium had failed to fulfil its obligations and, pursuant to Article 169 of the EC Treaty, sent the Belgian Government a letter of formal notice on 14 October 1992, calling upon it to submit its observations on the matter within two months.

4. In view of its failure to reply to the letter of formal notice and its continued failure to fulfil its obligations, the Commission addressed a reasoned opinion to the Belgian Government on 2 July 1993 in which it stated that the Kingdom of Belgium had failed to fulfil its obligations under Directive 90/385/EEC and urged that State to adopt

* Original language: Spanish.

1 — OJ 1990 L 189, p. 17.

within two months the measures necessary to comply with the reasoned opinion.

5. The Belgian Government neither replied to the reasoned opinion nor adopted the measures necessary in order to transpose Directive 90/385/EEC. The Belgian authorities merely informed the Secretariat General of the Commission by letter of 28 March 1995 that the draft national legislation intended to transpose the directive into Belgian law had been submitted for the opinion of the Conseil Supérieur d'Hygiène (Public Health Board).

6. In those circumstances, the Commission decided to bring the present action before the Court of Justice, asking it to declare that by failing to adopt the laws, regulations and administrative provisions necessary to comply with Council Directive 90/385/EEC or, in any event, failing to inform the Commission of them forthwith, Belgium had failed to fulfil its obligations under that directive and in particular Article 16 thereof. The Commission also asked that the Kingdom of Belgium be ordered to pay the costs.

7. In its defence, the Belgian Government did not dispute that it had failed to fulfil its obligations as alleged by the Commission and merely stated that the national provision implementing Directive 90/385/EEC had received favourable opinions 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 pending.

8. In the present case it has been indisputably demonstrated that Belgium did not adopt within the prescribed period the laws, regulations and administrative provisions necessary to comply with Council Directive 90/385/EEC. Accordingly, the Kingdom of Belgium has failed to fulfil its obligations under the third paragraph of Article 189 of the EC Treaty and Directive 90/385/EEC, in particular Article 16 thereof.

9. Since the Commission's application is well founded and must be upheld, the Kingdom of Belgium must be ordered to pay the costs, in accordance with Article 69(2) of the Rules of Procedure.

10. I therefore propose that the Court:

(1) Declare that, by failing to adopt and bring into force within the prescribed period the 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 the third paragraph of Article 189 of the EC Treaty and Article 16 of that directive.

(2) Order the defendant Member State to pay the whole of the costs of the proceedings.