

Case T-60/96

Merck & Co. Inc. and Others v Commission of the European Communities

(Free movement of goods — Transitional measures —
Act of Accession — Protective measures —
Pharmaceutical products — Action for annulment — Inadmissibility)

Order of the Court of First Instance (Fifth Chamber, Extended Composition),
3 June 1997 II - 853

Summary of the Order

1. *Actions for annulment — Natural or legal persons — Measures of direct and individual concern to them — Commission decision addressed to a Member State refusing the adoption of protective measures under Article 379 of the Act of Accession of Spain and Portugal — Legal character — Undertaking holding a patent filed in a Member State for a pharmaceutical product placed on the market in Spain — Inadmissible*
(EC Treaty, Art. 173, fourth para.; Act of Accession of Spain and Portugal, Arts 47 and 379)

2. *Actions for annulment — Natural or legal persons — Measures of direct and individual concern to them — Commission decision addressed to a Member State refusing the adoption of protective measures under Article 379 of the Act of Accession of Spain and Portugal — Undertaking holding a patent filed in a Member State for a pharmaceutical product placed on the market in Spain — Membership of a limited category of traders who are individually concerned — No such membership — Inadmissible*
(EC Treaty, Arts 30, 36 and 173, fourth para.; Act of Accession of Spain and Portugal, Arts 47 and 79)

3. *Actions for annulment — Natural or legal persons — Measures of direct and individual concern to them — Commission decision addressed to a Member State refusing the adoption of protective measures under Article 379 of the Act of Accession of Spain and Portugal — Undertaking holding a patent filed in a Member State for a pharmaceutical product placed on the market in Spain — Commission required to hear the views of the undertakings concerned before adopting the decision — No such obligation — Inadmissible*
(EC Treaty, Art. 173, fourth para.; Act of Accession of Spain and Portugal, Art. 379)

1. A Commission decision addressed to a Member State, refusing to authorize the adoption of protective measures with regard to pharmaceutical products coming from Spain pursuant to Article 379 of the Act concerning the conditions of accession of the Kingdom of Spain and the Portuguese Republic constitutes a legislative measure in relation to the undertakings concerned.

Undertakings holding a patent filed in a Member State for a pharmaceutical product placed on the market in Spain after its accession to the Community but before the product could be protected by a patent in Spain cannot be regarded as individually concerned by such decisions in the light of the criteria laid down by Article 173, fourth paragraph, of the Treaty.

Although the economic situation of those undertakings has been impaired by the fact that the situation brought about by the transitional period provided for in Article 47 of the Act of Accession has come to an end — that situation being one where the holder of a patent for a pharmaceutical product could, until the end of the third year after the new Member States had made those products patentable, rely upon the rights granted by that patent in order to prevent the import and marketing of pharmaceutical products placed on the market in Spain or Portugal for the first time by him or with his consent — that is not enough to differentiate them, in relation to the contested Decisions, from all other traders.

The status — on which one of the parties in the case relies — of being a party to proceedings before the national courts which have led to a preliminary ruling by

the Court in the course of which questions were raised which are linked to those concerning the validity of a measure contested before the Community judicature, is not sufficient in itself to distinguish the applicant individually in relation to that measure, since all traders in the same category as the applicant are entitled to bring an action before the national courts raising the same questions.

2. Traders who sell pharmaceutical products in Spain and in other Member States, whose products sold in Spain are protected by patents in the other Member States, are not members of a limited category of traders who, having regard to the criteria laid down by Article 173, fourth paragraph, of the Treaty, are individually concerned by Commission decisions addressed to Member States refusing authorization to adopt protective measures with regard to the products in question, pursuant to Article 379 of the Act concerning the conditions of accession of the Kingdom of Spain and the Portuguese Republic.

In order for it to be possible for the existence of a limited class of traders to be of relevance as a factor distinguishing the traders in question individually in relation to a contested act, three cumulative conditions must be satisfied. First, the traders in question must be in a situation which distinguishes them from all other traders concerned by the contested act. Secondly, the change in their situation — the factor which defines them by closing the limited class — must have its origin in

the adoption of the contested measure. Thirdly, the institution adopting the contested act must have been under an obligation to take account, at the time of the measure's adoption, of the particular circumstances of those traders.

Those three conditions are not satisfied in the present case. First, so far as concerns the first condition, membership of a limited category of pharmaceuticals manufacturers is not sufficient *per se* to differentiate the applicants' situation from that of all other producers of pharmaceutical products in the same category.

As regards the second condition, the change in the factual situation in which the applicants found themselves prior to the expiry of the transitional period provided for in Article 47 of the Act of Accession of Spain and Portugal is not a result of the adoption of the contested Decisions but of the expiry of the transitional period and the subsequent application of Articles 30 and 36 of the Treaty.

Lastly, as regards the third condition, the Commission has no obligation to take into account the special circumstances of those traders, since the adoption of a decision refusing authorization to take

protective measures does not have a sudden impact on market conditions and does not provoke disturbances on the market which are inherent in all protective measures.

3. Neither contact, whether direct or indirect, between the Commission and traders who sell pharmaceutical products in Spain and in other Member States, whose products in Spain are protected by patents in the other Member States, nor the participation of such traders in the procedure leading to the adoption of the Commission decisions refusing authorization to take protective measures pursuant to Article 379 of the Act of Accession of the Kingdom of Spain and the Portuguese Republic differentiates those traders from all other traders in relation to those Decisions.

The fact that a person participates in one way or another in the process leading to the adoption of a Community act does not distinguish that person individually in relation to the act in question unless the relevant Community legislation has laid down specific procedural guarantees for such a person.

In the context of the relevant provisions of the Act of Accession, there is no provision requiring the Commission, before adopting the decisions at issue, to follow a procedure during which persons in the category to which the traders in question belong would have the right to assert any rights or even to be heard.