22.10.2011 EN

The annulment of the Decision is accordingly sought on the grounds that it was adopted on the wrong legal basis, the consequence of which is that the United Kingdom has been deprived of its rights under Protocol 21.

(<sup>1</sup>) Council Decision 2011/407/EU of 6 June 2011 on the position to be taken by the European Union within the EEA Joint Committee concerning an amendment to Annex VI (Social Security) and Protocol 37 to the EEA Agreement OJ L 182, p. 12

Reference for a preliminary ruling from High Court of Justice (Chancery Division) (United Kingdom) made on 26 August 2011 — Novartis AG v Actavis UK Ltd

### (Case C-442/11)

(2011/C 311/44)

Language of the case: English

# **Referring court**

High Court of Justice (Chancery Division)

### Parties to the main proceedings

Applicant: Novartis AG

Defendant: Actavis UK Ltd

## Questions referred

Where a supplementary protection certificate has been granted for a product as defined by Regulation (EC) No 469/2009 (<sup>1</sup>) for an active ingredient, are the rights conferred by that certificate pursuant to Article 5 of the Regulation in respect of the subject matter as defined in Article 4 of the Regulation infringed:

- (i) by a medicinal product that contains that active ingredient (in this case valsartan) in combination with one or more other active ingredients (in this case hydrochlorothiazide); or
- (ii) only by a medicinal product that contains that active ingredient (in this case valsartan) as the sole active ingredient?

Appeal brought on 30 August 2011 by the European Commission against the judgment delivered by the General Court (Sixth Chamber, extended composition) on 16 June 2011 in Case T-196/06 Edison v Commission

(Case C-446/11 P)

(2011/C 311/45)

Language of the case: Italian

### Parties

Appellant: European Commission (represented by: V. Di Bucci and V. Bottka, agents)

Other party to the proceedings: Edison SpA

### Form of order sought

- Set aside the judgment of the General Court (Sixth Chamber, extended composition) of 16 June 2011, notified to the Commission on 20 June 2011;
- Refer the case back to the General Court for reconsideration;
- Reserve the decision on costs in both sets of proceedings;
- In the event that the Court finds that it can adjudicate on the substance, dismiss the action brought at first instance and order Edison SpA to pay the costs of both sets of proceedings.

### Pleas in law and main arguments

The Commission relies on four grounds in support of its appeal.

- (i) The General Court infringed Article 253 EC, in conjunction with Article 84 EC, in that it erred in its assessment of the purpose and scope of the obligation to state reasons with regard to the attribution of liability for infringements of Article 81 EC to the company holding all the capital in the company which participated directly in the infringement, which is based on a presumption which must be adequately rebutted. In particular, the General Court failed to take account of context and legal rules governing the matter, especially the burden of proof on the applicant. It erred in finding that the Commission was under a duty to state reasons in relation to arguments that were 'not insignificant', without requiring, as it should have required, that such arguments were capable of rebutting the presumption of liability on the part of the controlling company.
- (ii) In the alternative, the General Court infringed Articles 230 EC and 253 EC, in that it reached the conclusion that inadequate reasons were given for the contested decision. First, it erred in law in its reading of the contested decision, neglecting to consider certain relevant passages. Second, it confused issues of reasoning and issues of substance in refusing to take account of explanations provided in the contested decision, finding either that the Commission had acted in breach of the appellant's rights of defence, or that such explanations were not convincing.

<sup>(&</sup>lt;sup>1</sup>) Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products OJ L 152, p. 1