Reports of Cases

Case C-130/11

Neurim Pharmaceuticals (1991) Ltd
v
Comptroller-General of Patents

(Reference for a preliminary ruling from the Court of Appeal (England and Wales) (Civil Division))

(Medicinal products for human use — Supplementary protection certificate — Regulation (EC) No 469/2009 — Article 3 — Conditions for obtaining a supplementary protection certificate — Medicinal product having obtained a valid marketing authorisation — First authorisation — Product successively authorised as a veterinary medicinal product and a human medicinal product)

Summary of the Judgment

1. *Approximation of laws — Uniform legislation — Industrial and commercial property — Patent right — Supplementary protection certificate for medicinal products — Aim*

   (European Parliament and Council Regulation No 469/2009)

2. *Approximation of laws — Uniform legislation — Industrial and commercial property — Patent right — Supplementary protection certificate for medicinal products — Conditions for granting — Scope*

   (European Parliament and Council Regulation No 469/2009, Art. 3)

3. *Approximation of laws — Uniform legislation — Industrial and commercial property — Patent right — Supplementary protection certificate for medicinal products — Product protected by a basic patent in force — Products containing the same active ingredient having obtained successive market authorisations, first as a veterinary medicinal product and subsequently as a human medicinal product, by different proprietors — Request for a certificate for an application of a product for human use — Lawfulness — Conditions — Scope of protection conferred by the basic patent*

   (European Parliament and Council Regulation No 469/2009, Arts 3, 4 and 13(1); European Parliament and Council Directive 2001/83, Art. 8(3))

1. See the text of the decision.

(see paras 20, 22, 23)

2. See the text of the decision.

(see paras 20, 21, 25-27)

3. Articles 3 and 4 of Regulation No 469/2009 concerning the supplementary protection certificate for medicinal products must be interpreted as meaning that the mere existence of an earlier marketing authorisation obtained for a veterinary medicinal product does not preclude the grant of a supplementary protection certificate for a different application of the same product for which a marketing authorisation has been granted, provided that the application is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the supplementary protection certificate.

In those circumstances, Article 13(1) of Regulation No 469/2009 must be interpreted as meaning that it refers to the marketing authorisation of a product which comes within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the supplementary protection certificate.

Those answers would not be different if, in a situation such as that in the main proceedings where the same active ingredient is present in two medicinal products having obtained successive marketing authorisation, the second marketing authorisation required a full application in accordance with Article 8(3) of Directive 2001/83 on the Community code relating to medicinal products for human use, or if the product covered by the first marketing authorisation of the corresponding medicinal product is within the scope of protection of a different patent which belongs to a different registered proprietor from the supplementary protection certificate applicant.

(see paras 27, 31, 35, operative part 1-3)