# Order of the Court of 14 November 2013 (request for a preliminary ruling from the High Court of Justice (Chancery Division) — United Kingdom) — Astrazeneca AB v Comptroller General of Patents

**(Case C-617/12)** ([1])

***(Medicinal products for human use — Supplementary protection certificate — Regulation (EC) No 469/2009 — Article 13(1) — Concept of 'first authorisation to place [a product] on the market in the Community' — Authorisation issued by the Swiss Institute for Medicinal Products (Swissmedic) — Automatic recognition in Liechtenstein — Authorisation issued by the European Medicines Agency — Period of validity of a certificate)***

(2014/C 102/08)

*Language of the case: English*

## Referring court

High Court of Justice (Chancery Division)

## Parties to the main proceedings

*Applicant:* Astrazeneca AB

*Defendant:* Comptroller General of Patents

## Re:

Request for a preliminary ruling — High Court of Justice, Chancery Division, Patents Court — United Kingdom — Interpretation of Article 13(1) of 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 2009 L 152, p. 1) — Meaning of first authorisation to place the product on the market — Swiss authorisation automatically recognised by Liechtenstein but not granted in accordance with the administrative procedure laid down by Directive 2001/83/EC on the Community code relating to medicinal products for human use.

## Operative part of the order

*In the context of the European Economic Area (EEA), Article 13(1) of 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 must be interpreted as meaning that an administrative authorisation issued for a medicinal product by the Swiss Institute for Medicinal Products (SwissMedic), which is automatically recognised in Liechtenstein, must be regarded as the first authorisation to place that medicinal product on the market within the meaning of that provision in the European Economic Area where that authorisation predates marketing authorisations issued for the same medicinal product, either by the European Medicines Agency (EMA), or by the competent authorities of European Union Member States in accordance with the requirements laid down in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, and the authorities of the Republic of Iceland and the Kingdom of Norway. The fact that, on the basis of similar clinical data, the European Medicines Agency, unlike the Swiss authority, refused to grant a marketing authorisation for that medicinal product at the conclusion of its examination of those data, or the fact that the Swiss authorisation to place the product on the market was suspended by the Swiss Institute for Medicinal Products and subsequently reinstated by the latter only when the holder of the authorisation submitted additional data to it are irrelevant.*

([1]) OJ C 86, 23.3.2013.