European Union

“Merck Sharp”

**Decision of the European Court of Justice (Seventh Chamber)
7 December 2017 – Case No. C-567/16**

*Merck Sharp & Dohme Corporation v. Comptroller
General of Patents, Designs and Trade Marks*

**Regulation (EC) No 469/2009, Arts. 3(b), 10(3);
Directive 2001/83/EC, Art. 28(4)**

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Keywords Supplementary protection certificate · Medicinal products for human use · Conditions for obtaining · Grant or rejection · Basic patent · Marketing authorisation

1. Article 3(b) 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 is to be interpreted as meaning that an end of procedure notice issued by the reference Member State in accordance with Article 28(4) of 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, as amended, as regards pharmacovigilance, by Directive 2010/84/EU of the European Parliament and the Council of 15 December 2010, before the expiry of the basic patent, as defined in Article 1(c) of Regulation No 469/2009, may not be treated as equivalent to a marketing authorisation within the meaning of Article 3(b) of that regulation, with the result that a supplementary protection certificate may not be obtained on the basis of such a notice.
2. Article 10(3) of Regulation No 469/2009 is to be interpreted as meaning that the fact that no marketing authorisation has been granted by the Member State concerned at the time the supplementary protection certificate application is lodged in that Member State does not constitute an irregularity that can be cured under that provision.