



5 February 2010

**REGULATION (EC) 469/2009  
CONCERNING THE  
SUPPLEMENTARY PROTECTION  
CERTIFICATE FOR MEDICINAL  
PRODUCTS**

APPLICANT                      Sankyo Company Limited

ISSUE                              Whether application number  
SPC/GB/06/019 should be rejected  
under Article 10(2)

HEARING OFFICER              Dr L Cullen

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**DECISION**

1. This decision relates to application SPC/GB/06/019 for a supplementary protection certificate in the name of Sankyo Company Limited (“the applicant”) for the product defined at Article 6 of Form SP1 as “*A combination of olmesartan medoxomil, optionally in the form of a pharmaceutically acceptable salt, and hydrochlorothiazide*”.
2. The basic patent on which the patent relies is EP (UK) 0503785 with an earliest priority date of 21 February 1991, filed on 21 February 1992 and granted on 25 April 2001.
3. The examiner wrote to the applicant on 20 July 2006 stating that application no. SPC/GB/06/019 for a supplementary protection certificate for this product did not comply with the requirements of Article 3(a) of Council Regulation (EEC) 1768/92, this Regulation has since been superseded by Council Regulation (EC) 469/2009 (“the Regulation”). As a consequence of this, the applicant was informed that the application for a certificate should be refused under Article 10(2) of the Regulation.
4. The applicant did not respond to the Official letter dated 20 July 2006 within the period specified for reply. In a further Official letter dated 12 March 2007, the applicant was given an additional opportunity to respond to the objections raised in the earlier letter and informed that a failure to do so by 9 May 2007, would result in a Hearing Officer acting for the Comptroller deciding whether

the application should be rejected under Article 10(2) of the Regulation.

5. The applicant has not responded to the official letter and has not asked to be heard. In the absence of arguments to the contrary, I am satisfied that the conditions of the Regulation have not been met for this application. Therefore I reject this application under Article 10(2).

### **Appeal**

6. Under the Practice Direction to Part 52 of the Civil Procedure Rules, any appeal against this decision must be lodged within 28 days

**Dr L Cullen**

Deputy Director acting for the Comptroller