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Judgment in Case E-5/17 *Merck Sharp & Dohme Corp. v The Icelandic Patent Office*

THE SPC REGULATION PERMITS THE ISSUING OF A SUPPLEMENTARY PROTECTION CERTIFICATE OF NEGATIVE DURATION

In a judgment delivered today, the Court answered a question referred to it by the Supreme Court of Iceland (*Hæstiréttur Íslands*), concerning the interpretation of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (“the SPC Regulation”).

The SPC Regulation allows patent holders to apply for a supplementary protection certificate (“SPC”), which grants an additional period of exclusivity after the patent expires. An SPC is intended to compensate for the delay to commercial exploitation of a pharmaceutical invention that is caused by the procedure of obtaining a marketing authorisation. The objective is to ensure that a patent provides sufficient effective protection in order to encourage pharmaceutical research. An SPC may have a duration of up to five years, corresponding to the period between the date of the application for the basic patent and the date of the first marketing authorisation in the EEA minus five years.

Merck Sharp & Dohme Corp. (“Merck”) filed an application for an SPC with the Icelandic Patent Office in September 2007. The period between the application date of Merck’s basic patent (July 2002) and the grant of the first marketing authorisation (March 2007) was less than five years. The Patent Office rejected the application because the SPC would then have a negative duration, which it found incompatible with, inter alia, the purpose of the SPC Regulation. In September 2015, the Board of Appeal for Industrial Intellectual Property Rights (*Áfrýjunarnefnd hugverkaréttinda á sviði iðnaðar*) upheld the Patent Office’s decision. Merck challenged this decision before the Icelandic courts. The question referred to the Court concerned whether the SPC Regulation permits the grant of an SPC of negative duration. In particular, the referring court pointed to the fact that Regulations (EC) Nos 1901/2006 and 469/2009, which provide for a six-month extension of certain SPCs, thereby giving a purpose to SPCs of negative duration, have not been incorporated into the EEA Agreement.

The Court held that it follows from the SPC Regulation that where the application for an SPC meets the conditions listed, the competent authority shall grant the certificate. Nothing in the wording of the provisions of the SPC Regulation suggests that it precludes an SPC of negative duration. A positive duration is not listed among the conditions for obtaining a certificate, and a negative duration is not among the valid reasons for rejection. The SPC Regulation thereby not only allows for the issuing of an SPC of negative duration, it requires the competent authorities in the EEA to issue an SPC where the conditions for granting the certificate are fulfilled.

The grant of an SPC of negative duration is consequently permissible under the SPC Regulation and a competent authority cannot reject an application merely because an SPC’s duration is not positive.

The full text of the judgment may be found on the internet at: www.eftacourt.int.

This press release is an unofficial document and is not binding upon the Court.