Case C-181/95

Biogen Inc.
v
Smithkline Beecham Biologicals SA

(Reference for a preliminary ruling
from the Tribunal de Commerce, Nivelles)

(Council Regulation (EEC) No 1768/92 — Supplementary protection certificate
for medicinal products — Refusal by the holder
of the marketing authorization to provide a copy
to the applicant for the certificate)

Summary of the Judgment

1. *Approximation of laws — Uniform legislation — Industrial and commercial property — Patent right — Supplementary protection certificate for medicinal products — Medicinal product protected by several basic patents — Entitlement of each basic patent holder to a certificate*

(Council Regulation No 1768/92, Arts 1(c), 3(c) and 6)

2. *Approximation of laws — Uniform legislation — Industrial and commercial property — Patent right — Supplementary protection certificate for medicinal products — Conditions for obtaining — Provision of a copy of the marketing authorization — Obligation of the holder of the marketing authorization to provide a copy to the holder of a basic patent — None — Right of the competent national authority to refuse to grant a certificate failing presentation by the applicant of a copy of the authorization — Excluded*

(Council Regulation No 1768/92, Art. 8(1)(b))

1. Regulation No 1768/92 concerning the creation of a supplementary protection certificate for medicinal products, which was adopted to make up for the insufficiency of the effective protection under the patent to cover the investment put into the pharmaceutical research, provides that the certificate may be obtained by the holder of a national or European patent under the same conditions in each Member State. Article 6 of that regulation confirms that the certificate is to be granted to the holder of the basic patent or his successor in title, and Article 1(c) mentions the basic patents which may be designated for the purpose of the procedure for the grant of a certificate, namely those which protect a product as such, a process to obtain a product or an application of a product. The regulation thus seeks to confer supplementary protection on the holders of such patents, without instituting any preferential ranking amongst them.

   Consequently, where a medicinal product is covered by several basic patents, the regulation does not preclude the grant of a supplementary protection certificate to each holder of a basic patent, subject to the proviso that, in accordance with Article 3(c), only one certificate may be granted for each basic patent.

2. Regulation No 1768/92 concerning the creation of a supplementary protection certificate for medicinal products does not require the holder of the marketing authorization to provide the holder of a patent which constitutes a basic patent for the medicinal product in question with a copy of that authorization.

   Whilst under Article 8(1)(b) of that regulation an application for a supplementary protection certificate must contain a copy of the marketing authorization for the medicinal product, there is nothing in the regulation requiring the holder of that authorization to provide the basic patent holder with a copy of it. Exercise of the right to obtain a certificate referred to in Article 6 of the Regulation is in no way dependent on a discretionary act on the part of the holder of the marketing authorization. The regulation does not, however, preclude such an obligation from resulting from the contractual relationship between the holder of the patent and the holder of the marketing authorization.

   Nevertheless, the purpose of the requirement imposed by Article 8(1)(b) is simply

to identify the product and verify that the time-limit for submitting an application and, where applicable, the duration of the supplementary protection are observed. It is therefore merely a formal requirement whose purpose is to demonstrate the existence of an authorization to place the product on the market as a medicinal product.

Consequently, where the basic patent and the authorization to place the product on the market as a medicinal product are held by different persons and the patent holder is unable to provide the competent national authorities with a copy of that authorization in accordance with that provision, the application for a certificate must not be refused on that ground alone, since by virtue of the mutual cooperation incumbent on the various national authorities the national authority which is competent to grant the certificate can obtain a copy of the marketing authorization from the national authority which issued it.