The supplementary protection certificate for « medicinal products » (Regulation 1768/92) and for « plant protection products » (Regulation 1610/96)

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Screening process
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Internal Market & Services DG

Origin of the SPC's

- "Thalidomide disaster" in the late 50's.

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- **Marketing authorization** (M.A.): European Authorities decided to establish controls before medicines and "plant protection products" were placed in the market [1]

- Any M.A. is granted by the competent national authorities for the territory of each MS or by a EU centralised procedure (EMEA)

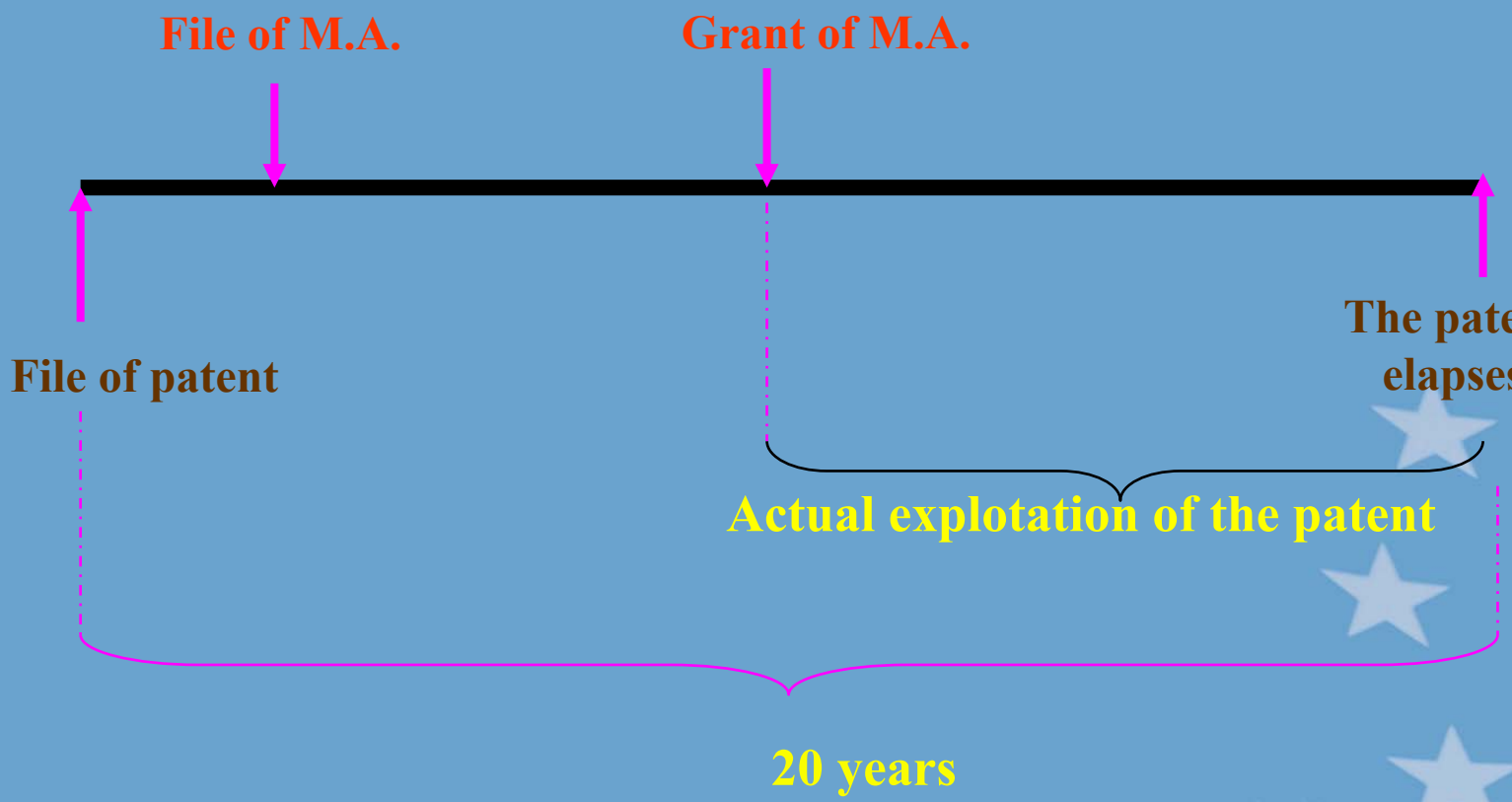
- In order to get the M.A., many clinical trials and information must be arranged and submitted by the applicant. It can take years

[1] Directive 65/65/EEC (amended by Directive 2001/83/CE and the new pharmaceutical package Directive 2004/27/EC, and Directive 81/851/ECC for medicines) and Directive 91/414/EEC for plant protection products

Marketing authorizations and patents

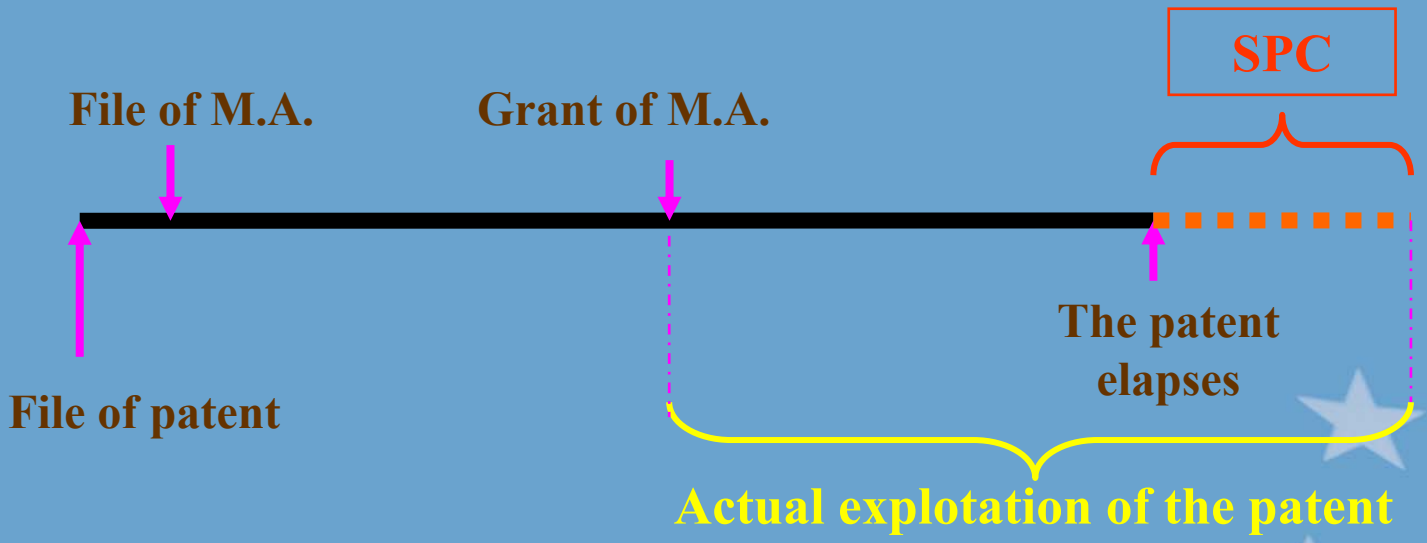
- Patents must be filed before any public disclosure of the invention is made
- The M.A. is applied after the submission of the patent
- The granting procedure of the M.A. takes years and in the meantime, the patent cannot be exploited !!
- And, the patent is granted for 20 years from its lodge date
- Therefore, patent protection in the pharmaceutical sector is much less effective
- This could lead to less research in the EU pharma sector

Marketing Authorizations and patents



What is a SPC?

- The SPC extends the protection conferred by the patent beyond its 20-year term for a period of up to 5 years



- But, only in respect of a product which has received a M.A. in the particular Member State
- It does not extend the term of the patent itself

Objectives of the SPC's Regulations

- Improvement in the public health and the production of food
- Not to hamper European **innovation** in the pharmaceutical and plant protection sectors
- Find a uniform solution throughout the EU internal market
- Find a balance between the compensation of the results of long and costly research and the **public health expenditure**

Both Regulations are very similar. The Regulation 1610/96 amends and clarifies some provisions of the Regulation 1768/92

Provisions of the SPC's Regulations

- **Scope:** a SPC may be granted to any product protected by a patent in a MS and subject to a M.A. (Article 2)

- The SPC is granted to the holder of the basic patent or his successor in title (Art 6)

- Conditions for obtaining the SPC in each MS (Article 3):
  - the product is protected by a basic **patent** in force;
  - a valid **[marketing] authorization** to place the product on the market [of the MS where the application is filed] as a medicinal product ....;
  - the product has not already been the subject of a certificate [to prevent accumulation of SPCs on the same patent];
  - the authorization referred to in (b) is the **first authorization** …."

Provisions of the Regulations 1768/92 and 1610/96

- **Lodging**, **publication** and **grant** of the SPC application (Art 7,9,11): in the Patent Office of each MS. Application within 6 months after the "grant date" of the M.A. (normally)

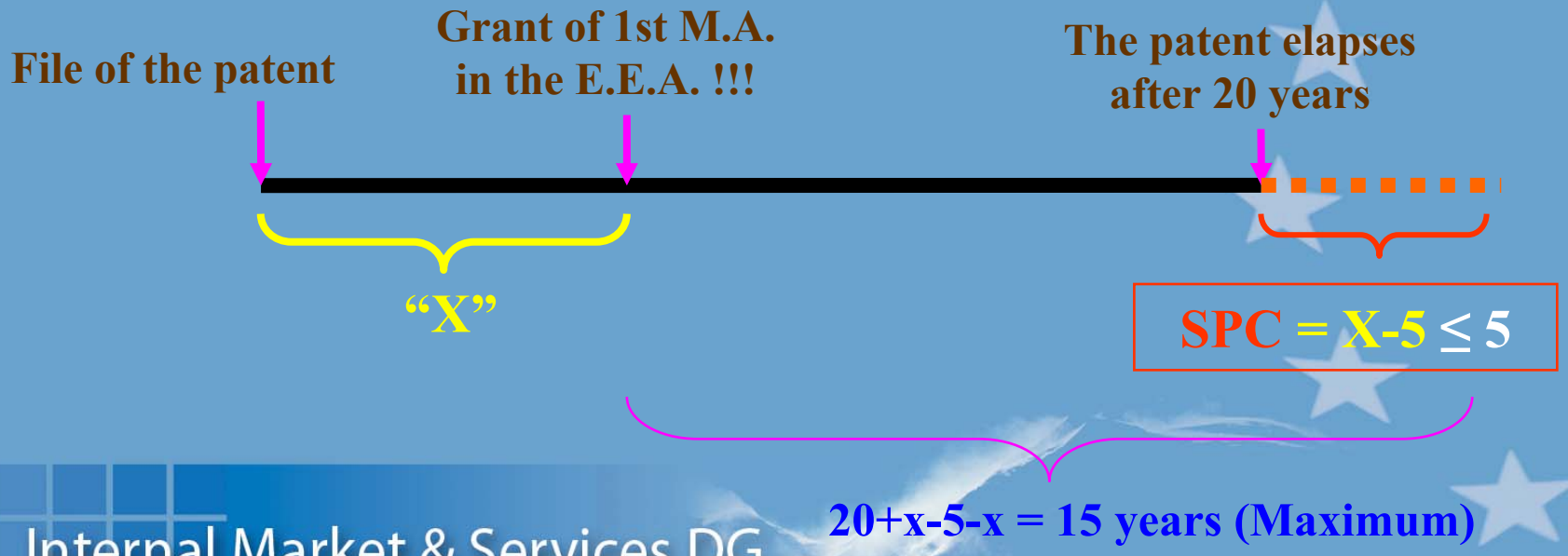
- The granting procedure is a **National procedure** within the framework established by the Regulation. Every MS Office is free to charge fees (Art 12)

- Content of the SPC application (Art 8): mainly applicant's data and proof of fulfilling substantive requirements of Article 3

- Subject-matter of protection and **effects of the SPC**: it extends only to the product covered by the M.A. and for any authorized use of the product as a medicinal product within the limits of the protection conferred by the basic patent (Art 4,5)

Provisions of the Regulations 1768/92 and 1610/96

- The **duration** of the SCP cannot exceed 5 years (Art 13)
  - It takes effect at the end of the lawful term of the patent
  - for a period equal to the period which elapsed between the patent application's date and the date of the first M.A. granted in the E.E.A. reduced by a period of 5 years



Case-law and future initiatives

- There are some preliminary ruling already judged and some pending.
- Amendment proposed by 52004PC0559: **Paediatric Regulation**

For further information:

http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31992R1768&model=guicheti