



Making Medicines Affordable

Myths and Realities

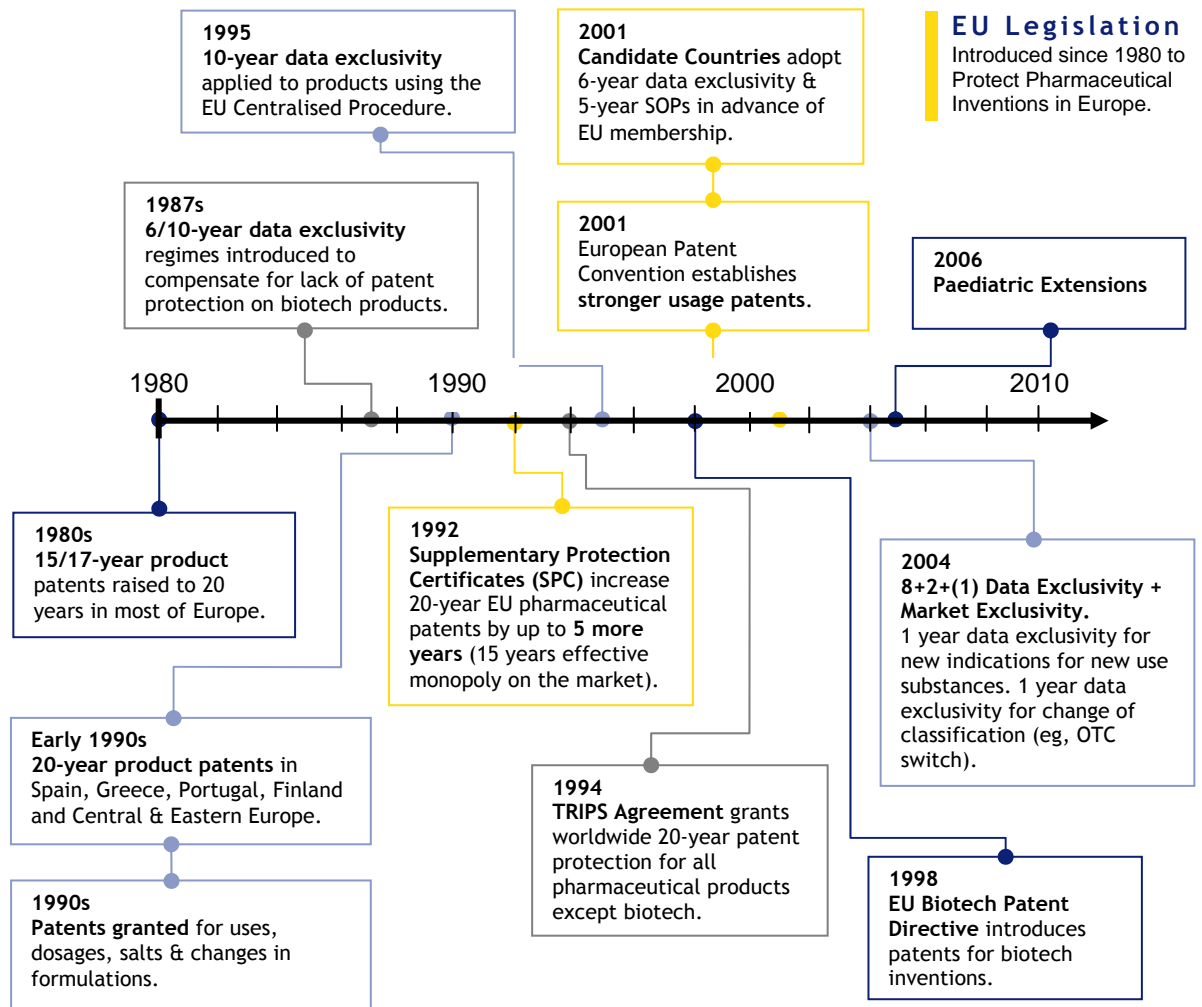
of the pharmaceutical industry

Myth

Patents in Europe do not give enough protection to pharmaceutical research.

& Reality

IP protection on pharmaceutical inventions in Europe is the *strongest* in the world.





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Pharmaceutical Patents

Patents are used to protect a product, process, apparatus or use that has a practical purpose. Registration provides a patentee the right to prevent anyone making, using, selling, or importing the invention for 20 years. Any given pharmaceutical product is typically protected by 20-40 different patents on various aspects and properties of the product.

Supplementary Protection Certificates (SPC)

Supplementary Protection Certificates (SPCs) grant “patent extensions” of up to 5 years to pharmaceutical products, providing as much as 25 years of patent life for originator medicines.

Data Exclusivity

Data exclusivity prevents medicines regulators from accepting an application for a marketing authorisation based on bioequivalence during a defined period. In the EU the so-called “8+2 +1” formula applies to all new medicinal products if the application was submitted after 31 October 2005. In these cases generic medicines companies can apply for a marketing authorisation based on bioequivalence only after the 8-year data exclusivity period has expired, and can only market their products two or three years after that. The effective period of marketing exclusivity is therefore 10 or 11 years.

Formed in 1993, the EGA is the official representative body of the European generic pharmaceutical industry, which is at the forefront of providing high-quality affordable medicines to millions of Europeans and stimulating competitiveness and innovation in the global pharmaceutical sector.