Supplementary Protection Certificates

Patentability of pharmaceutical inventions
European Patent Academy ● IGO_IFJ (Belgian Judicial Training Institute)
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Pierre Véron
Honorary President EPLAW (European Patent Lawyers Association)
Member of the Expert Panel group of the Unified Patent Court
Member of the Drafting Committee of the Rules of Procedure

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Overview

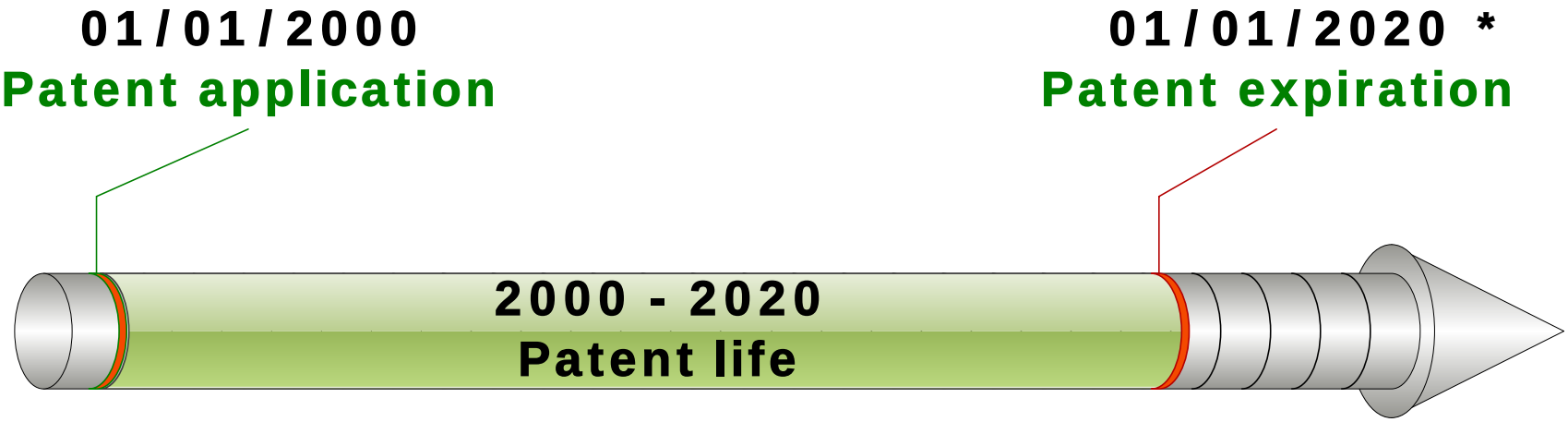
Supplementary Protection Certificate

- SPCs are a unique (*sui generis*) intellectual property right that constitute an extension (of up to 5 years) to the term of a patent right (of 20 years)
- SPCs apply to innovative pharmaceutical and plant protection products that have been protected by a patent and authorized by regulatory authorities
- They aim to offset the loss of effective patent protection that occurs due to the compulsory and lengthy testing and clinical trials that such products require prior to obtaining regulatory marketing approval

1. Why a supplementary protection for pharmaceutical products?

- Supplementary Protection Certificates were introduced in Europe to encourage innovation by compensating for the long time needed to obtain regulatory approvals (marketing authorization) for medicaments
- Available in the US and Japan as "Patent Term Extension"

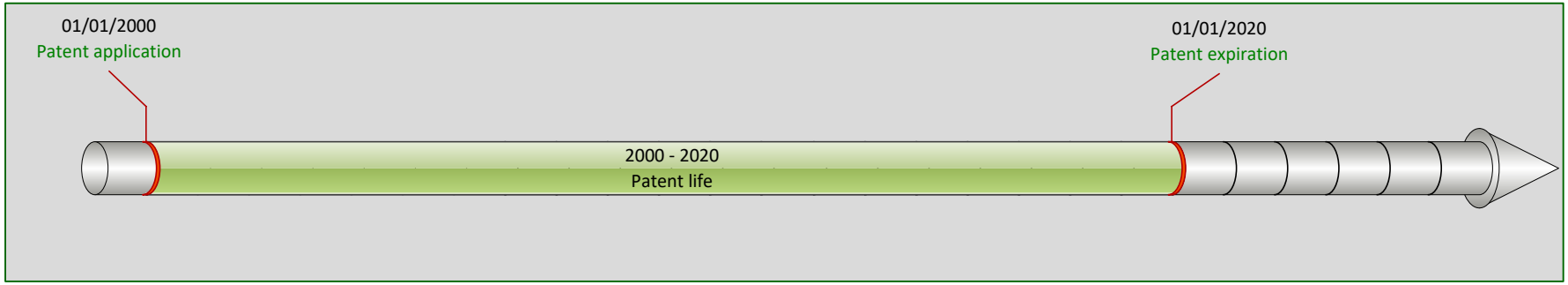
Patent life: the law

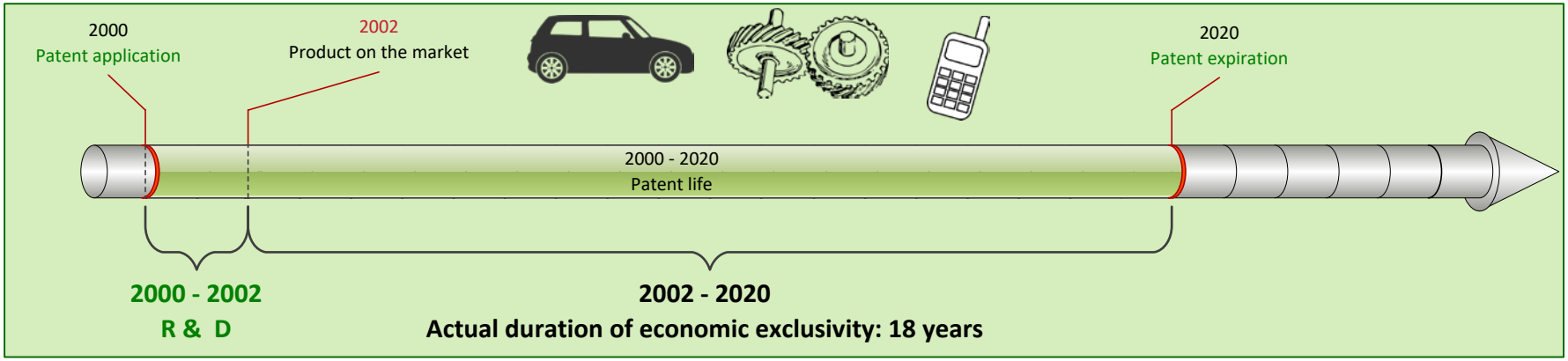


Patent protection lasts 20 years

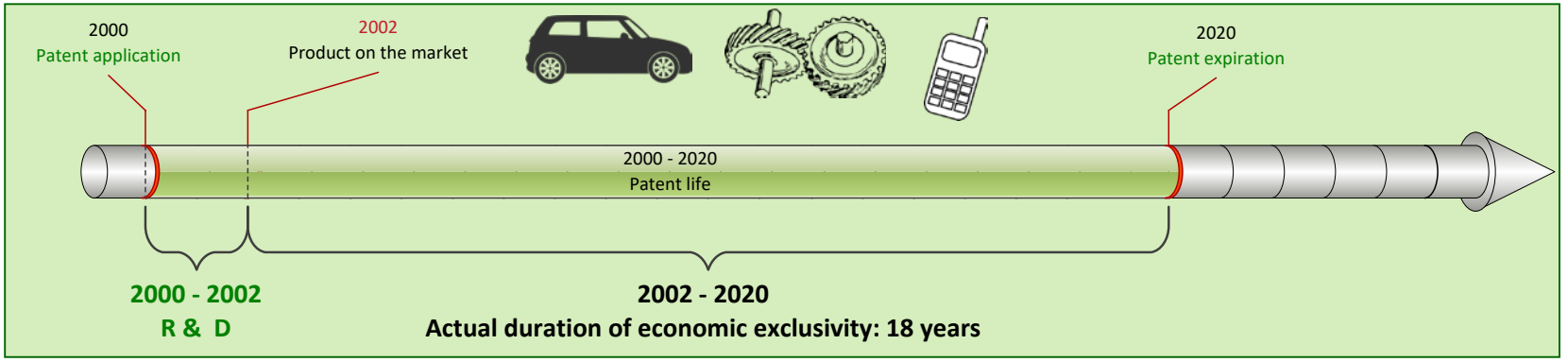
* more precisely: 01/01/2020 00:00:00

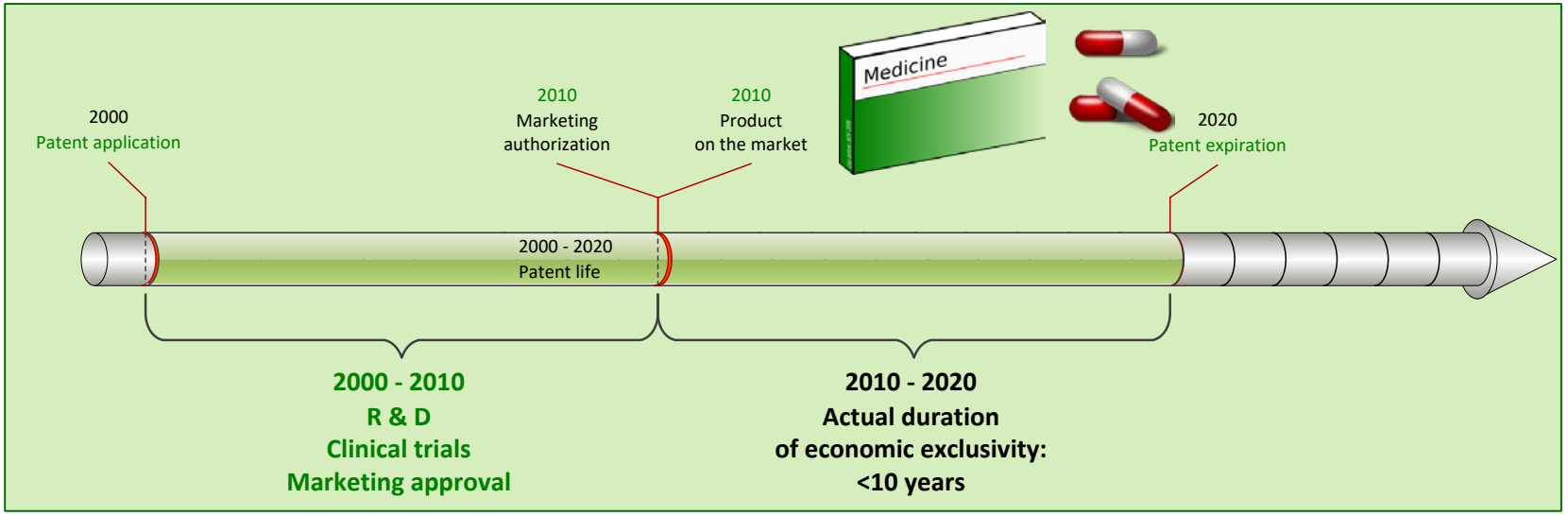
Patent life: the economics mechanics, telecom, etc.



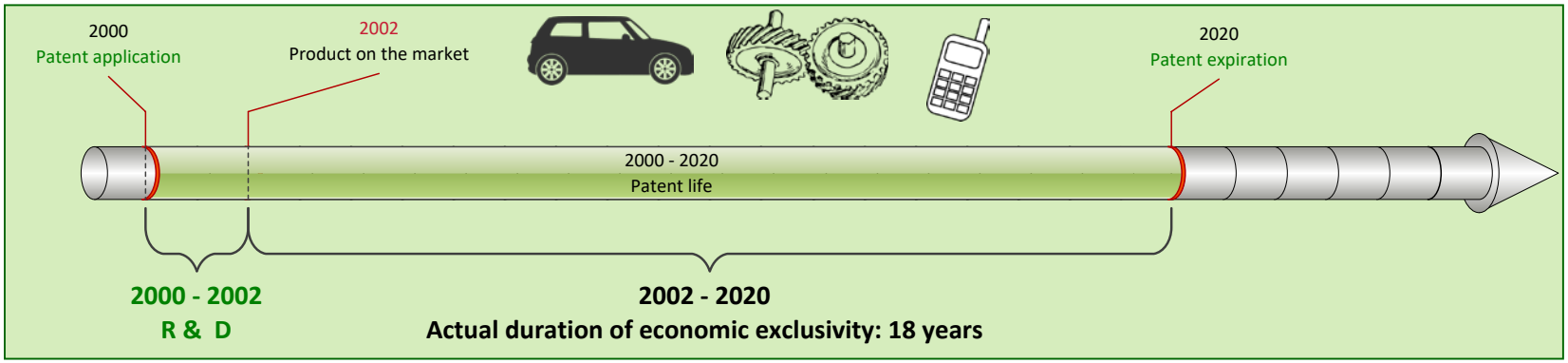


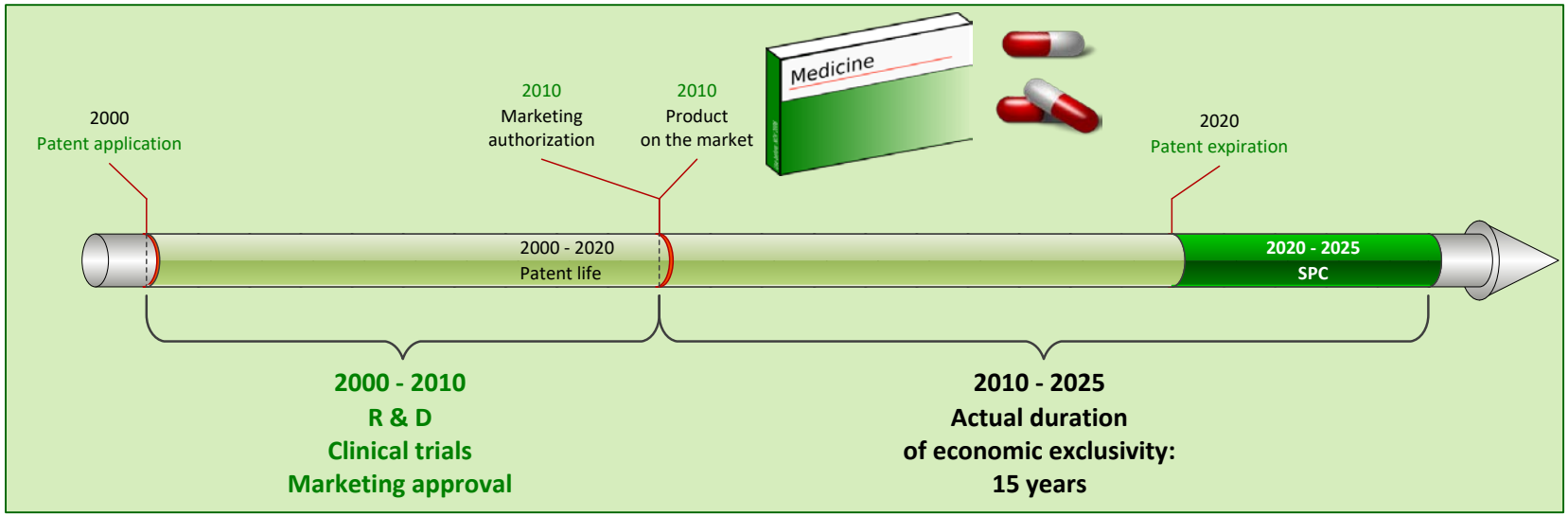
Patent life: the economics pharma <u>without</u> SPC



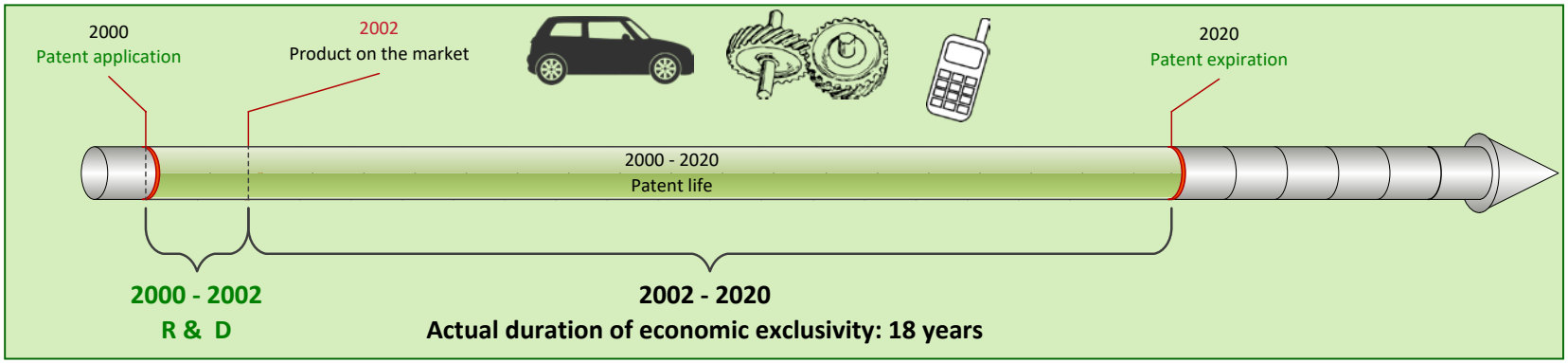


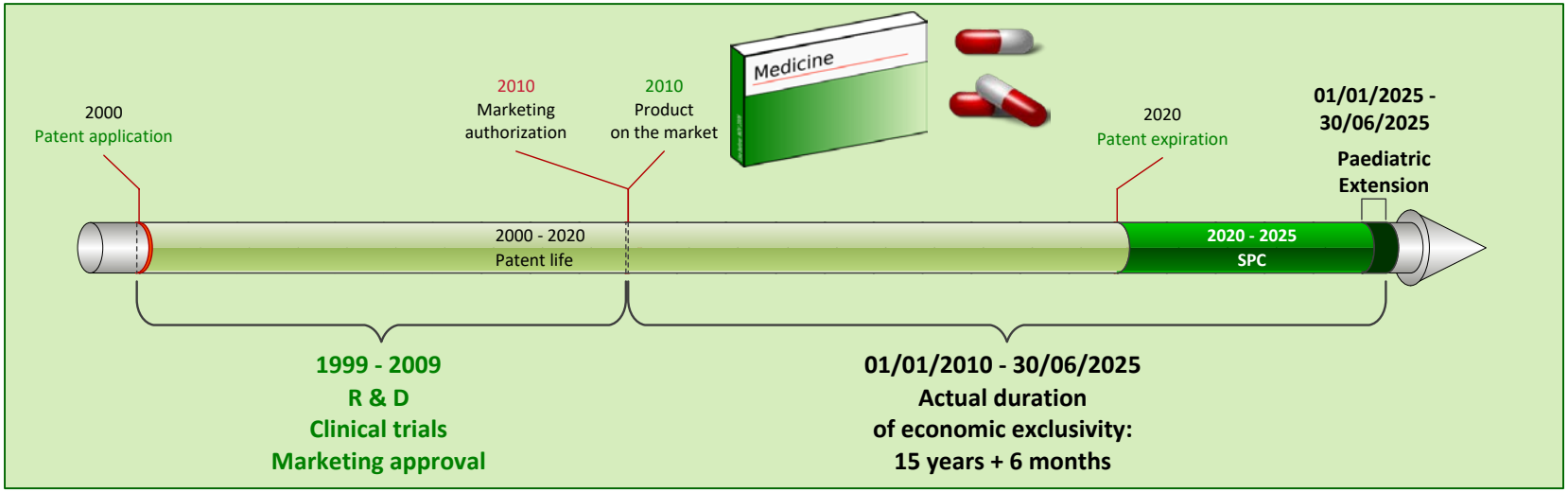
Patent life: the economics pharma <u>with</u> SPC



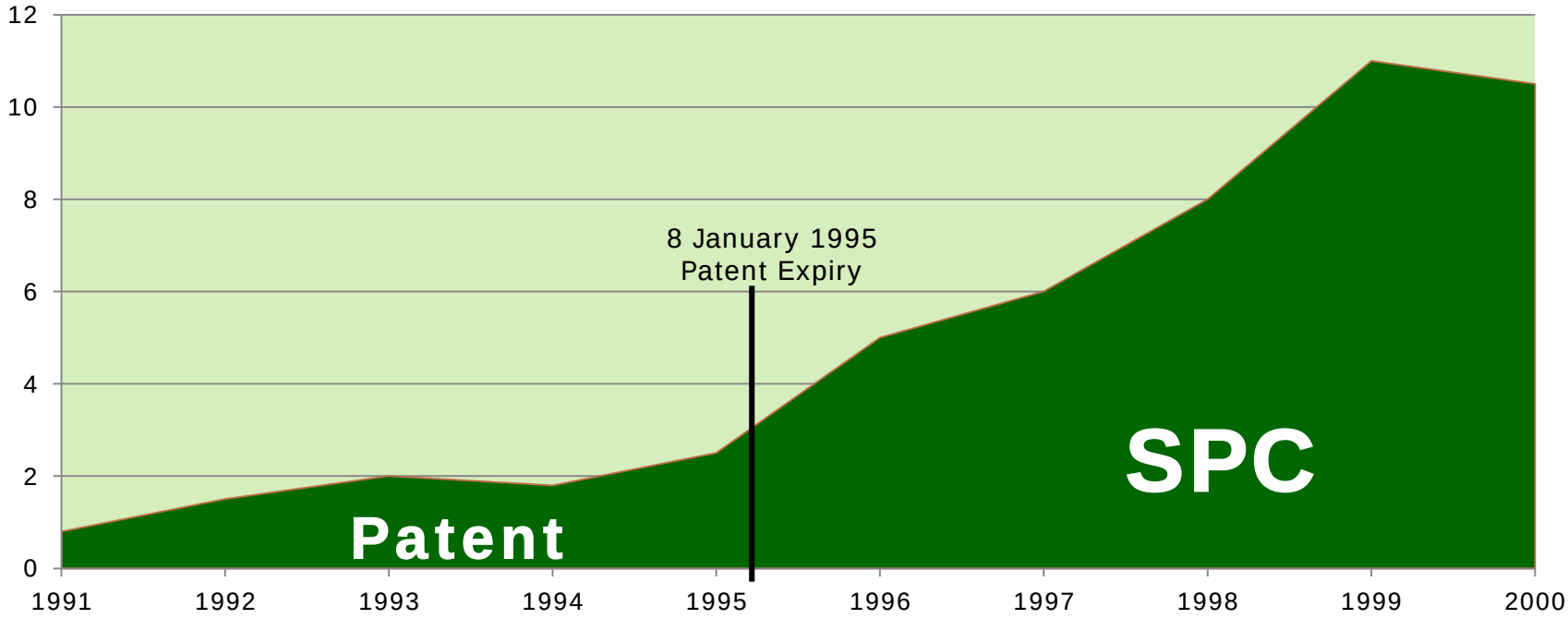


Patent life: the economics
pharma with SPC
+ Paediatric Extension of the SPC





Paramount $ importance of SPC



80% of the sales of the anti-depressor Prozac in the UK have been made after the patent expiry

Paramount $ importance of SPC

Gilead is the holder of the European patent (UK) EP 0 915 894 ('the basic patent at issue'). The patent application, filed on 25 July 1997, had a priority date, for the purposes of Article 88 of the EPC, of 26 July 1996. That patent was granted by the European Patent Office (EPO) on 14 May 2003 and expired on 24 July 2017. The description of the invention contained in that patent

In 2012, the FDA approved the use of Truvada for PrEP, a daily pill that prevents the transmission of HIV. In the United States, Truvada is currently sold at a list price of approximately $2,100 per month, generating $3 billion in revenue for Gilead in 2018 alone. Generic Truvada is available in other countries at a fraction of the cost, but no generic version is offered in the United States.

Information in connection with the judgment handed down on 25 July 2018 by the CJEU about the antiretroviral drug Truvada® (Teva v. Gilead)

2. EU regulations on SPCs

- Regulation (EC) Nº 469/2009 (codifying Regulation 1768/92) is a **EU Regulation**

- But the SPCs are **granted nationally** by the national patent offices (DE SPC, FR SPC, NL SPC, UK SPC, etc.): one application for each Member State where an SPC is requested

The possible future creation of a

European SPC title?

12 October 2017

EU Commission launches a Public consultation on supplementary protection certificates (SPCs) and patent research exemptions

https://ec.europa.eu/info/consultations/public-consultation-supplementary-protection-certificates-spcs-and-patent-research-exemptions_en

- the creation of a European SPC title (Unitary SPC)
- an update of the scope of EU patent research exemptions
- the introduction of an SPC “manufacturing waiver” (manufacturing for export outside the EU)

Introduction of an
SPC “manufacturing waiver”

Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products introduces

- an SPC “*manufacturing waiver*” (manufacturing for export outside the EU)

- a “*stockpiling exemption*” (manufacturing 6 months before SPC expiry for sale in EU after SPC expiry)

Article 2
Regulation (EC) Nº 469/2009

"***Any product protected by a patent*** *in the territory of a Member State and* ***subject, prior to being placed on the market as a medicinal product, to an administrative authorization procedure*** *as laid down in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (2) or Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (3)* ***may****, under the terms and conditions provided for in this Regulation,* ***be the subject of a certificate***."

Regulation (EEC) № 1610/96 concerning SPC for plant protection products

- Recital (13):

  « *(13) Whereas the certificate confers the same rights as those conferred by the basic patent; whereas, consequently, where the basic patent covers an active substance and its various derivatives (salts and esters),* ***the certificate confers the same protection****;* »

- Recital (17):

  « *(17) Whereas the detailed rules in recitals (…), 13 (…) of this Regulation are also valid, mutatis mutandis, for the interpretation in particular of (…) Article 4 (…) of Council Regulation (EEC) № 1768/92.* »

Paediatric extension of SPCs

The duration of the SPC can, however, be extended to 5 years **plus 6 months** when the SPC relates to a human medicinal product for which data from clinical trials conducted in accordance with an agreed Paediatric Investigation Plan (PIP) have been submitted

(Article 36 of Regulation (EC) Nº 1901/2006).

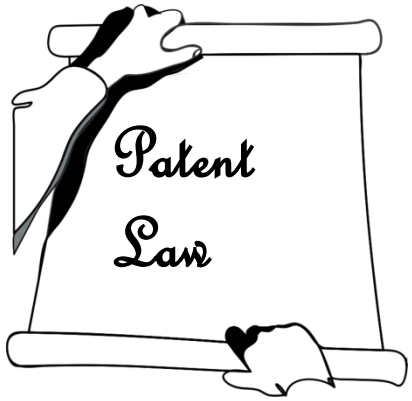
SPC prerequisites

- A patent

- A drug
  with a marketing authorization

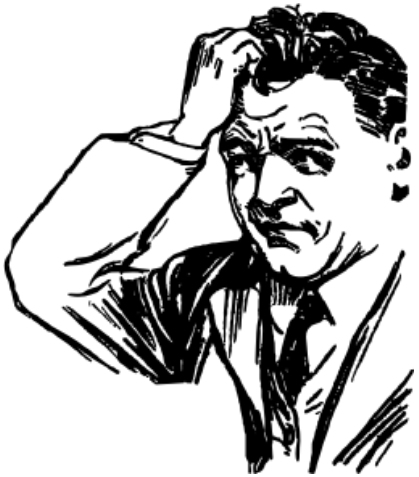
SPC

SPC legal framework



SPC

SPC: a complex legal area



+ 7 cases pending

3. Formal conditions for obtaining an SPC

- Who can file?
- When to file?
- Where to file?

Who can file the SPC?

Article 6 **Entitlement to the certificate**

- *"The certificate shall be granted to the holder of the basic patent or his successor in title".*

- Patent holder vs. Marketing Authorization holder?
  When the basic patent and the Marketing Authorization are held by different entities, the patent proprietor may apply without the consent of the Marketing Authorization holder
  CJEU, Case C-181/95, 23/01/97, **Biogen** / Smithkline]

When the SPC application should be filed?

Article 7 **Application for a certificate**

"*The application for a certificate shall be lodged within six months of the date on which the authorization referred to in Article 3(b) to place the product on the market as a medicinal product was granted*".

When the SPC application should be filed?

The Liechtenstein case

"*In so far as an authorisation to place a medicinal product on the market issued by the Swiss authorities and automatically recognised by the Principality of Liechtenstein under that State's legislation is* ***the first authorisation to place that product on the market in one of the States of the European Economic Area****, it constitutes the first authorisation to place the product on the market within the meaning of Article 13 of Council Regulation (EEC) Nº 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, as it is to be read for the purposes of the application of the Agreement on the European Economic Area*"

CJEU, Case C-181/95, 21/04/2005, **Novartis** C-207/03 and C-252/03

Where the SPC application should be filed?

- One application for each Member State where an SPC is requested; the SPC applications must be filed in the respective national patent offices:
  - Deutsches Patent- und Markenamt for DE SPC
  - United Kingdom Intellectual Property Office for UK SPC
  - Institut National de la propriété industrielle for FR SPC
  - Octrooicentrum Nederland for NL SPC...
- No European SPC (Unitary SPC) at the moment (work in progress; public consultation launched 12 October 2017 by EU Commission)

4. Substantive conditions for obtaining an SPC

Regulation (EC) № 469/2009
Article 3 Conditions for obtaining a certificate

a) the product is protected by a basic patent in force;

b) a valid authorisation to place the product on the market as a medicinal product has been granted;

c) the product has not already been the subject of a certificate;

d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

Medicinal products

- Drugs
- Vaccines
- Diagnosis products acting *in vivo*
  (no SPC for product acting *in vitro*)
- Medical device: SPC not available except when the medical device includes an active medicinal product
  However a stent coated with a drug is not eligible for a SPC when the drug was not assessed as a medicinal product, but was assessed, for intended use as an accessory of the medical device

  CJEU, Case C-527/17, 25/10/2018, Boston Scientific

The product must be “protected” by the basic patent

Article 3 a) of Regulation № 469/2009

“*the product is protected by a basic patent in force within the meaning of Article 3 a)*”

Which product can be designated in the SPC?

Article 1 b) of Regulation № 469/2009:

- The active ingredient of the drug
- The combination of active ingredients of the drug
- More?

Article 3(a)

The product is "protected" in any of the forms covered by the basic patent

"*where a product in the form referred to in the marketing authorization is protected by a basic patent in force, the supplementary protection certificate is capable of covering the product, as a medicinal product, in* ***any of the forms enjoying the protection of the basic patent****.*

2. In order to determine, in connection with the application of Regulation Nº 1768/92 and, in particular, Article 3(a) thereof, whether a product is protected by a basic patent, reference must be made to the rules which govern that patent."

CJEU, Case C-392/97, 16/09/1999, **Farmitalia** Carlo Erba (Idarubicin)

Combination products

The “Disclosure Test” vs the “Infringement Test”

1. The “Disclosure Test”:

The combination must be **disclosed or identifiable** in the basic patent
(GB, FR , DE, SE)

2. The “Infringement Test”

The combination must **infringe** the patent pursuant to Article 69 EPC
(CH, NO, CZ)

Combination products

Medeva C-322/10

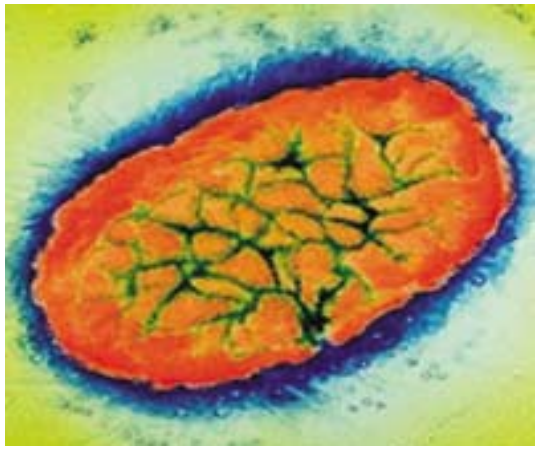
Basic patent

Method claim for the preparation of an acellular *B. pertussis* vaccine

Marketing Authorization

Multi-vaccine against:

- Whooping cough
- Diphtheria
- Tetanus
- Polio
- Meningitis



Combination products

The Medeva test

*"1. the competent industrial property office of a Member State (may **not** grant) a supplementary protection certificate relating to active ingredients which are **not specified in the wording of the claims** of the basic patent relied on in support of the application for such a certificate.*

*2. the competent industrial property office of a Member State (may grant) a supplementary protection certificate for a combination of two active ingredients, corresponding to that **specified in the wording of the claims** of the basic patent relied on, where the medicinal product for which the marketing authorization is submitted in support of the application for a supplementary protection certificate contains not only that combination of the two active ingredients **but also other active ingredients**."*

CJEU, Case C-322/10, 24/11/2011, **Medeva**

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Tenofovir (Gilead's drug Truvada®)

- Preliminary injunction denied in DK and FR because the SPC's combination of tenofovir disoproxil (as fumarate) and emtricitabine was not "*protected by the basic patent*",

- SPC held valid in CH: the Swiss court refused to adopt the CJEU's "Medeva" line of decisions. As a consequence, Swiss SPCs will be assessed based on the infringement test. No additional criteria, such as "*specified in the wording of the claims*" (Medeva), "*the claims relate, implicitly but necessarily* ..." (Eli Lilly), "*core inventive advance* ..." (Actavis) or the like are to be applied.

CJEU, Case C-121/17, 25/07/2018, **Teva v. Gilead**

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Tenofovir (Gilead's drug Truvada®)

"*a product composed of several active ingredients with a combined effect is* 'protected by a basic patent in force' *within the meaning of Article 3(a) of Regulation No 469/2009 where, even if the combination of active ingredients of which that product is composed is not expressly mentioned in the claims of the basic patent, those claims relate necessarily and specifically to that combination…*"

CJEU Grand Chamber, Case C-121/17, 25/07/2018, Teva v. Gilead

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Tenofovir (Gilead's drug Truvada®)

"For that purpose, from the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basic patent:

– the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and

– each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent."

CJEU Grand Chamber, Case C-121/17, 25/07/2018, Teva v. Gilead

Regulation (EC) Nº 469/2009 Article 3

Further conditions for obtaining a certificate

a) the product is protected by a basic patent in force;

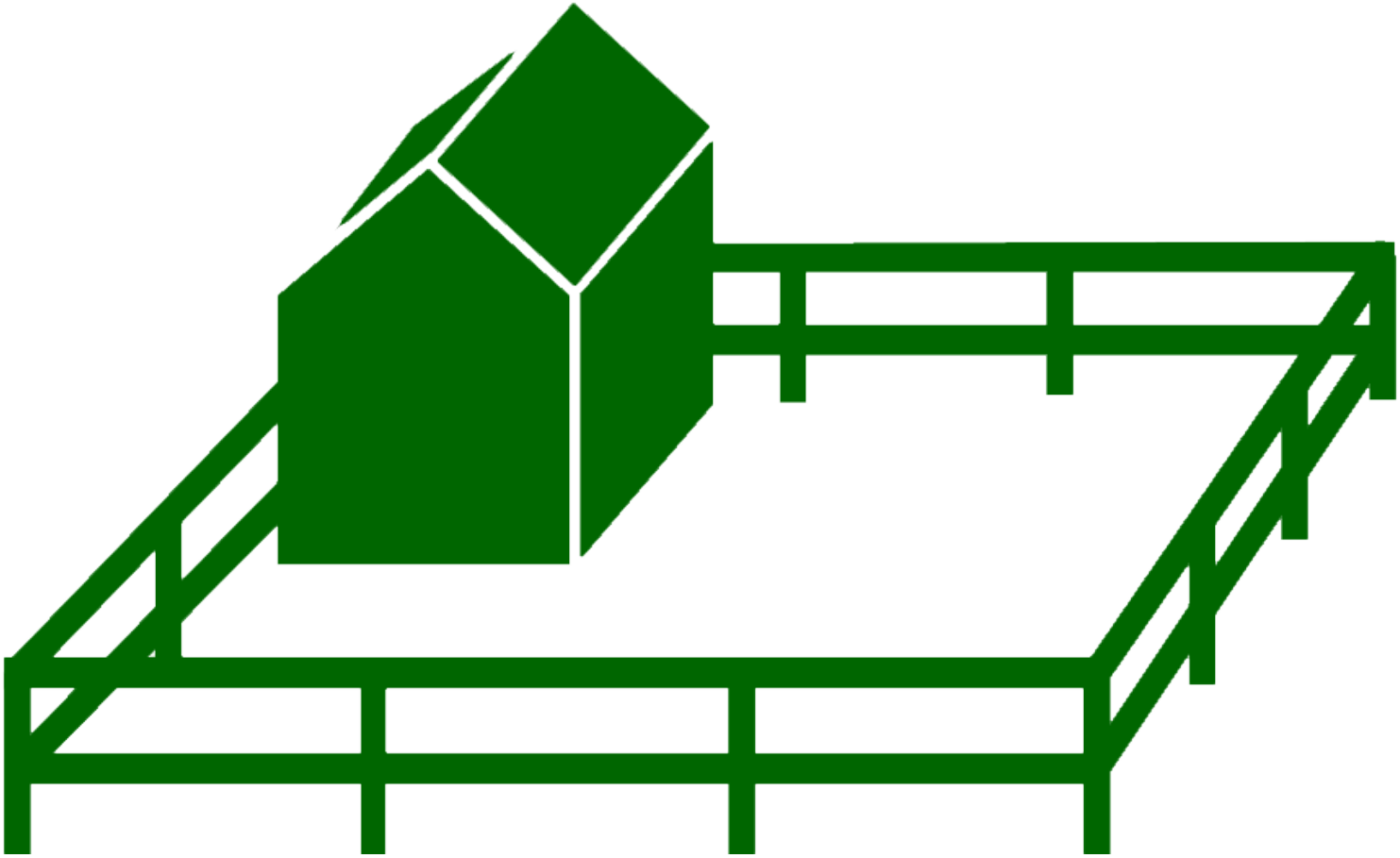
b) a valid authorisation to place the product on the market as a medicinal product has been granted;

c) the product has not already been the subject of a certificate;

d) the authorisation referred to in point (b) is the first authorization to place the product on the market as a medicinal product*.

* CJEU, Case C-443/17, 21/03/2019, Abraxis

5. Scope of the SPC



Scope of protection

Is the scope of an SPC designating the active ingredient A:

- limited to the drugs having A as active ingredient?
- or comparable to the scope of a patent claiming A?

Scope of protection
Regulation № 469/2009

- Article 4, « *Subject-matter of protection* »:

  « *Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorization to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorized before the expiry of the certificate.* »

- Article 5, « *Effects of the certificate* »:

  « *Subject to the provisions of Article 4, the certificate shall confer the* ***same rights as conferred by the basic patent*** *and shall be subject to the same limitations and the same obligations.* »

Scope of protection: combination products

"*where a 'product' consisting of an active ingredient was protected by a basic patent and the holder of that patent was able to rely on the protection conferred by that patent for that 'product' in order to oppose the marketing of a medicinal product containing that active ingredient in combination with one or more other active ingredients,*
a supplementary protection certificate *granted for that 'product'* ***enables its holder****, after the basic patent has expired,* ***to oppose the marketing by a third party of a medicinal product containing that product for a use of the 'product'****, as a medicinal product, which was authorized before that certificate expired."*

CJEU, case C-442/11, 09/02/2012 **Novartis** v Actavis UK

6. Duration of SPCs

Art 13 states that the duration of an SPC is:

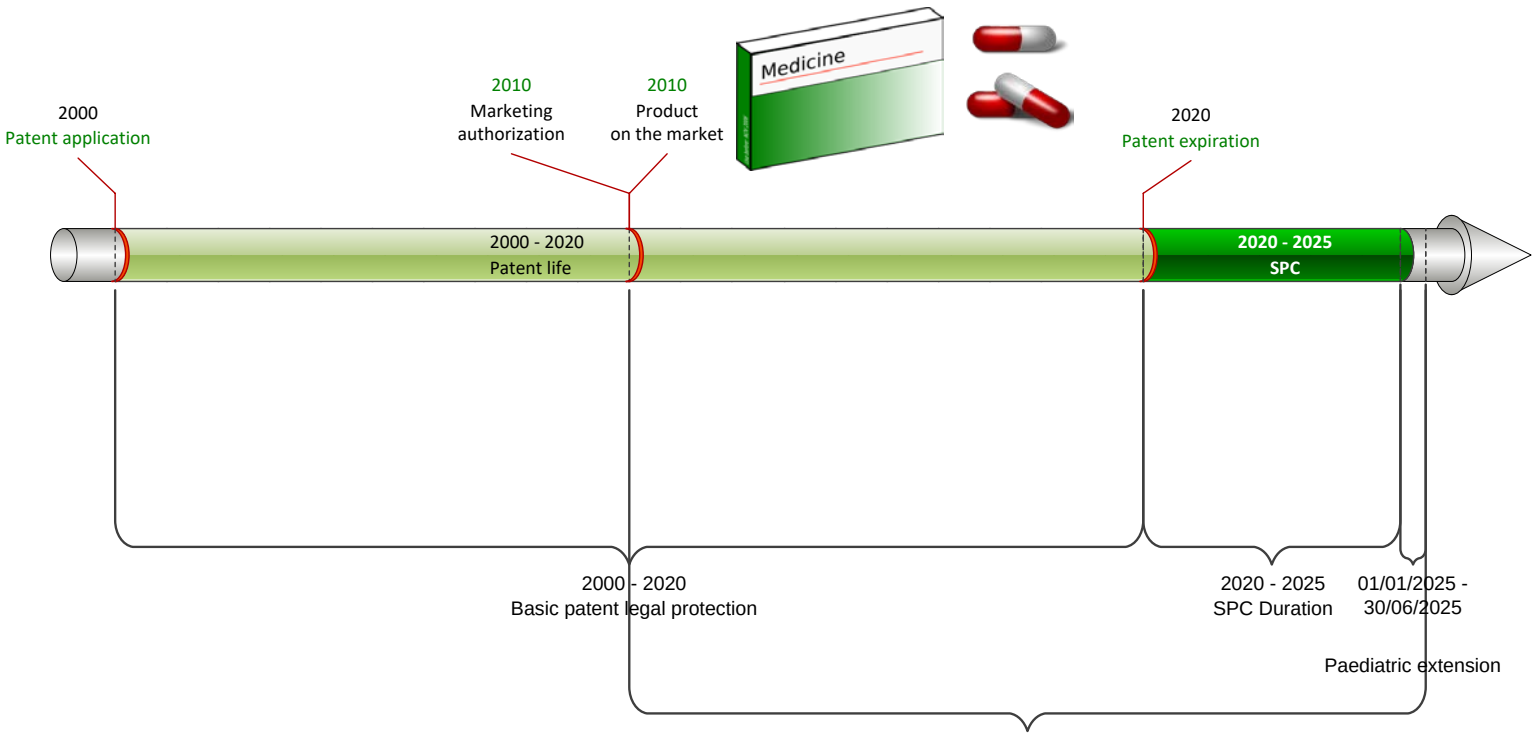
"... equal to the period which elapsed between

- *the date on which the application for a basic patent was lodged and*
- *the date of the first authorisation to place the product on the market in the Community*
- *reduced by a period of five years"*

Duration of SPCs

- The maximum duration of the SPC is 5 years (+ 6 months if paediatric extension applies)
- The SPC covers every medical use of the product authorized before its expiration

Duration of SPCs



2010 - 2025

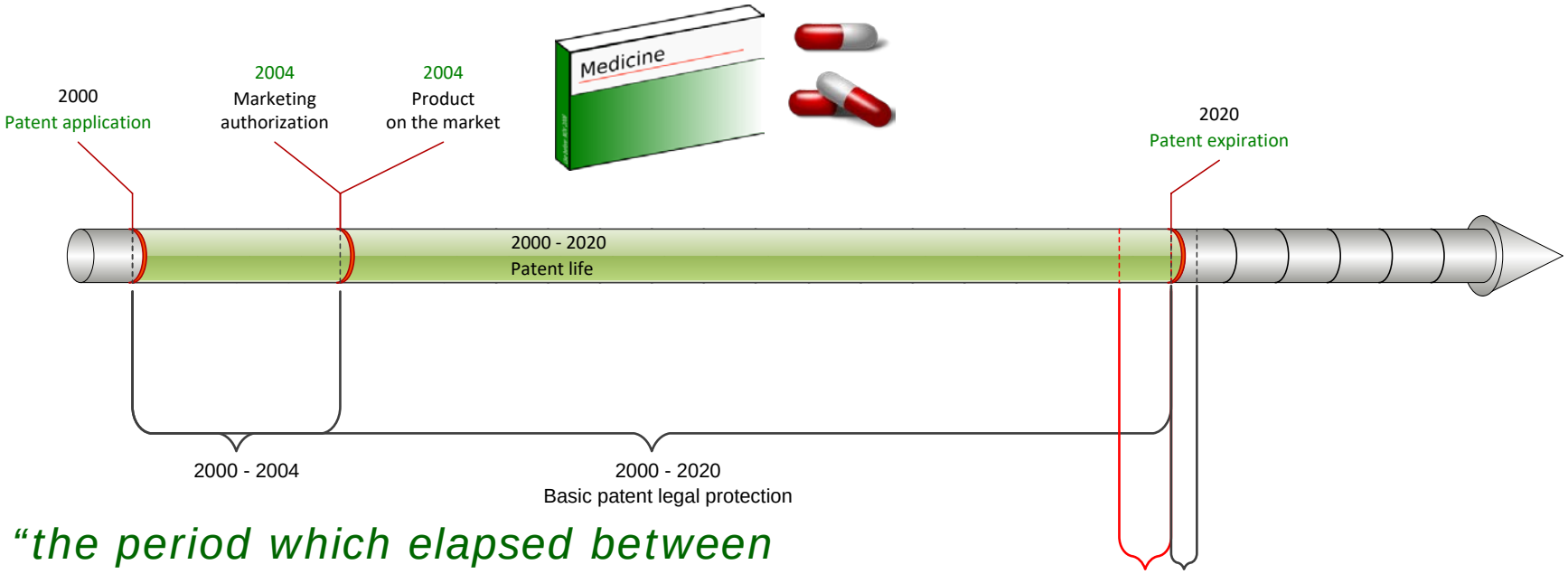
Actual duration of economic exclusivity: 15 years + 6 months

Paediatric extension

Consequences of the 6-month SPC extension include:

- the maximum term of an SPC can be up to 5 years **and 6 months**; and
- the maximum duration of market exclusivity (patent + SPC) can be up to 15 years **and 6 months**.
- An extension of an SPC can only be awarded if there is an SPC to extend; as an SPC only has a positive term if more than 5 years have elapsed between patent filing and marketing authorization issuance, this causes the so called “negative duration” scenario when the marketing authorization has been granted less that 5 years after the patent application date

"*Negative duration*" SPCs for a paediatric extension



"the period which elapsed between the date on which the application for a basic patent was lodged (01/01/2000) and the date of the first authorization to place the product on the market in the Community (01/01/2004)
reduced by a period of five years"

The Merck decision accepts "*negative duration*" SPC

"… ***medicinal products can be the object of the grant of a supplementary protection certificate where the period*** *that has elapsed between the date of lodging the basic patent application and the first marketing authorization in the European Union* ***is less than five years****. In such a case, the period of the paediatric extension provided for by the latter regulation starts to run from the date determined by deducting from the patent expiry date the difference between five years and the duration of the period which elapsed between the lodging of the patent application and the grant of the first marketing authorization*"

Case C-125/10, 8 December 2011, **Merck Sharp & Dohme**

Pierre Véron

Thank you

pierre.veron@veron.com
www.pierre-veron.com