Panel Discussion 4:
BALANCING DATA AVAILABILITY AND NEED TO KNOW;
Data protection, availability of information to researchers and best practices

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Types of Exclusivity in Pharmaceutical Industry

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Type of Exclusivity	Details / Examples
Specific Market Factors	e.g. not attractive from profit side? // Combivent® (CFC) USA?
Know How Exclusivity	depends on technology / Catapress TTS / Respimat® ?
Regulatory Exclusivity - data protection - market exclusivity - re-examination periods	Concerns originator exclusivity periods with regard to a third party's generic marketing authorization application referencing the same.
Patent Exclusivity -SPC / PTR (PTE) - Ped. exclusivity	Technical IP: Only available for technical inventions. The patent allows its owner to forbid another persons to use his invention.

Regulatory Exclusivity

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Originator Exclusivity Periods*

- Regulatory exclusivity was designed to promote a balance between new drug innovation and generic drug competition.

- Drug regulatory authorities cannot rely upon the originator's test data for an approved drug product in order to approve generic applications during a pre-determined period of time**

- Applies automatically, no application necessary, no fees

Basis: TRIPS/ Section 7

** *http://www.cptech.org/publications/CPTechDPNo1TestData.pdf*

Regulatory Exclusivity

Two types of "Protection Periods" may be distinguished

Data Exclusivity (DE)

Period during which Regulatory Authority will not process a generic MAA that references originator's data.

Such generic MAA must be submitted after end of said data exclusivity period.

Regulatory Authority review follows thereafter.

Market Exclusivity (ME)

Period during which applicants for a generic product cannot market their product.

Europe: market exclusivity follows data exclusivity period

Regulatory Exclusivity

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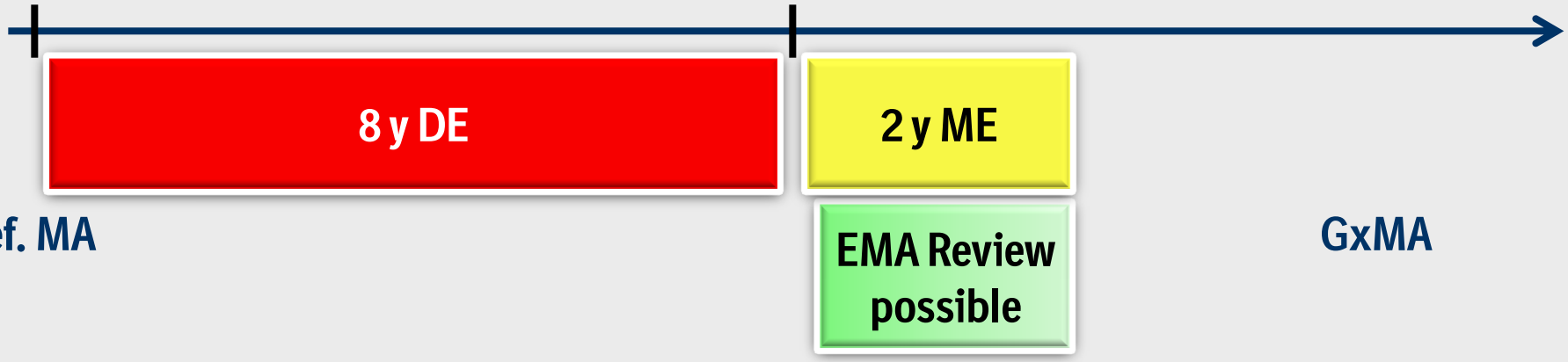
Reg. Exclusivity period Europe: Example NCE



If within 8 y DE holder obtains MA for an indication of significant clinical benefit: **+ 1 y ME**

Regulatory Exclusivity

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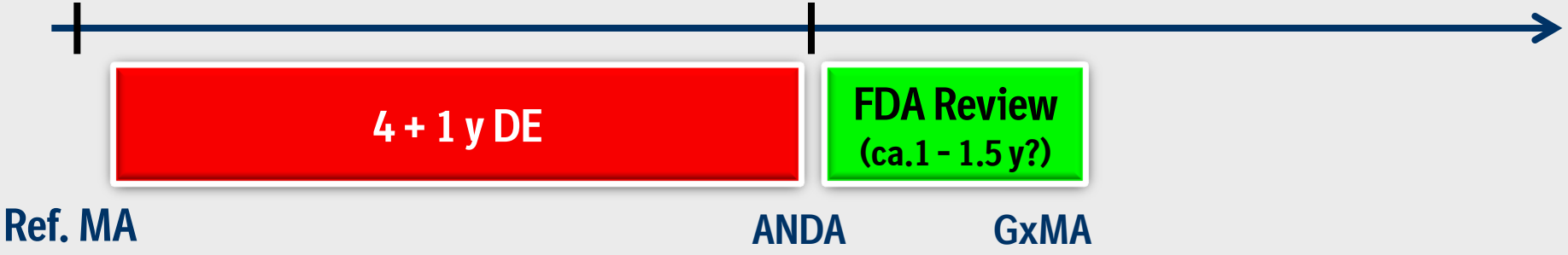
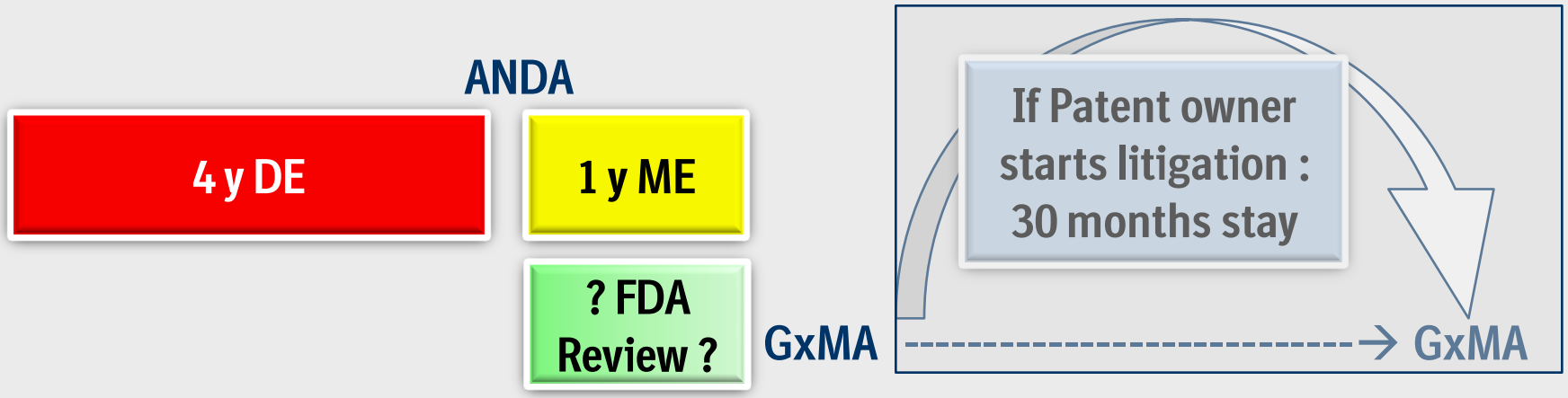
Reg. Exclusivity period US: Example NCE

Scenario 1: Orange Book does not list patent rights 4 years post MA- ANDA Paragraph I Cert.



Scenario 2: Orange Book lists patent rights 4 years post MA - ANDA Paragraph IV Cert.



Orange Book: http://www.fda.gov/default.htm

Terms of Regulatory Protection

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NMEs

Europe	Σ_{max} 11 y NMEs	8 y DE + 2 y ME + 1 y ME
USA*	Σ_{max} 5.5 y NCEs	NCE: 5y DE, opt. + 0.5 PE ANDA: 4 y DE + 1 y ME; opt. + PE that adds on 4 y term

* Possible patent litigation and 30 months stay not considered

* FDA review period not considered

Japan	Σ_{max} 8 - 10 y NMEs	re-examination* after 8 y (10 y if pediatric data provided), exact time is set by Health Authority ** re-examination: Health Authority „revisits" the review process*

The missing link - Europe

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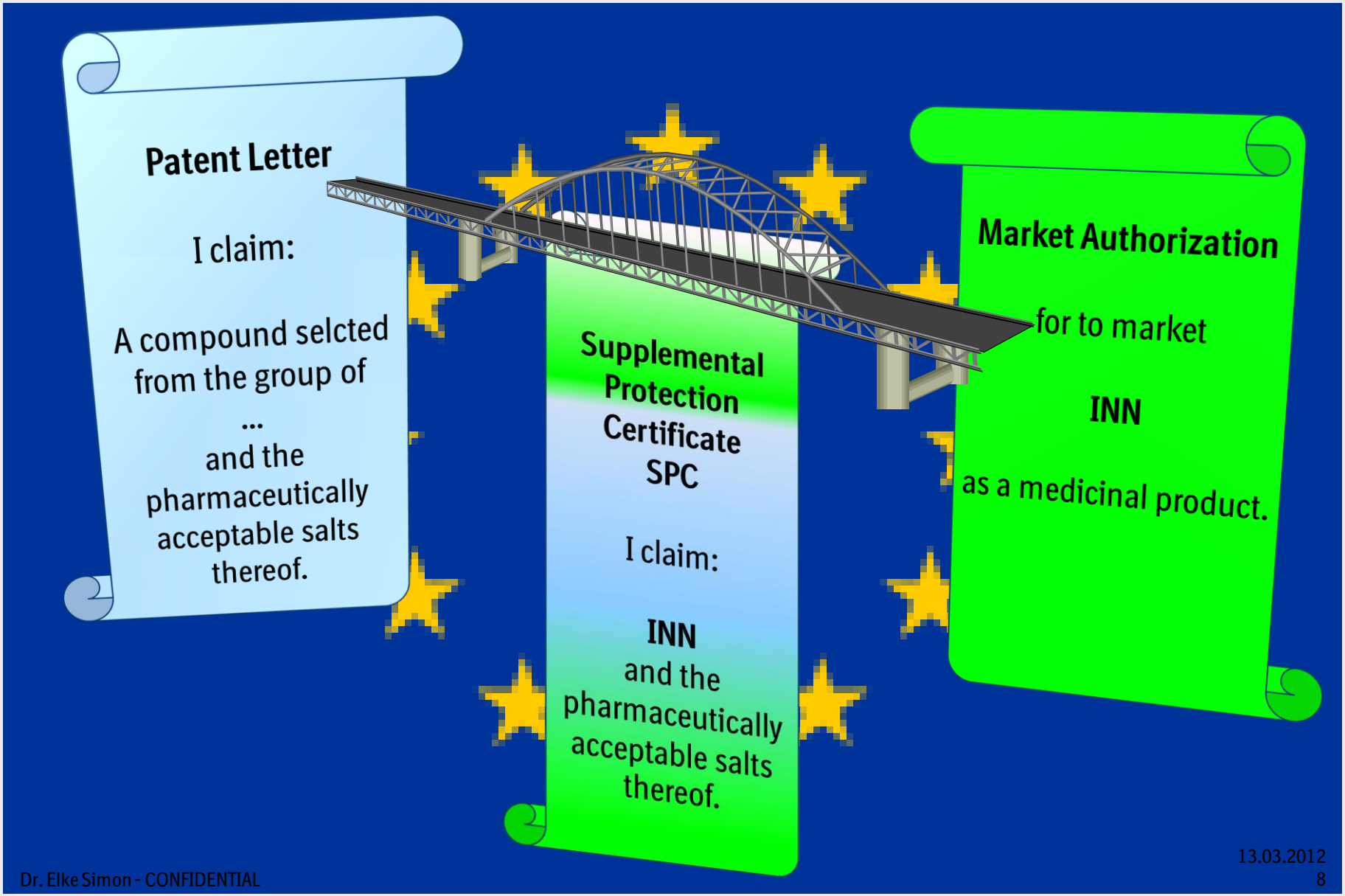

SPC - EUROPE

- is a **national** right *sui generis*
- requires an existing MA
- is a „supplemental“ patent-like right for a marketed drug product
- same rights as patent but limited to authorized API(s) – to the extend (specifically) covered by patent
- is limited to a term of max. 5 years

SPC Term - EUROPE

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A fictive mind set which helps understanding SPC term calculation

An innovate new drug development starts with filing a patent application.
Development is finished if new drug product is Authorized for Marketing.
⇒**Patent filing date and MA are corner stones of a new drug development.**

Five years of development are no undue burden for the pharmaceutical industry.
⇒**Compensation of time only, if development exceeds 5 y.**

Post- MA exclusivity shall not exceed 15 years (15.5 years if ped. exclusivity is considered)
A maximum compensation of 5 years is sufficient.
⇒**Term of compensation must not exceed 5 y.**

SPC Term

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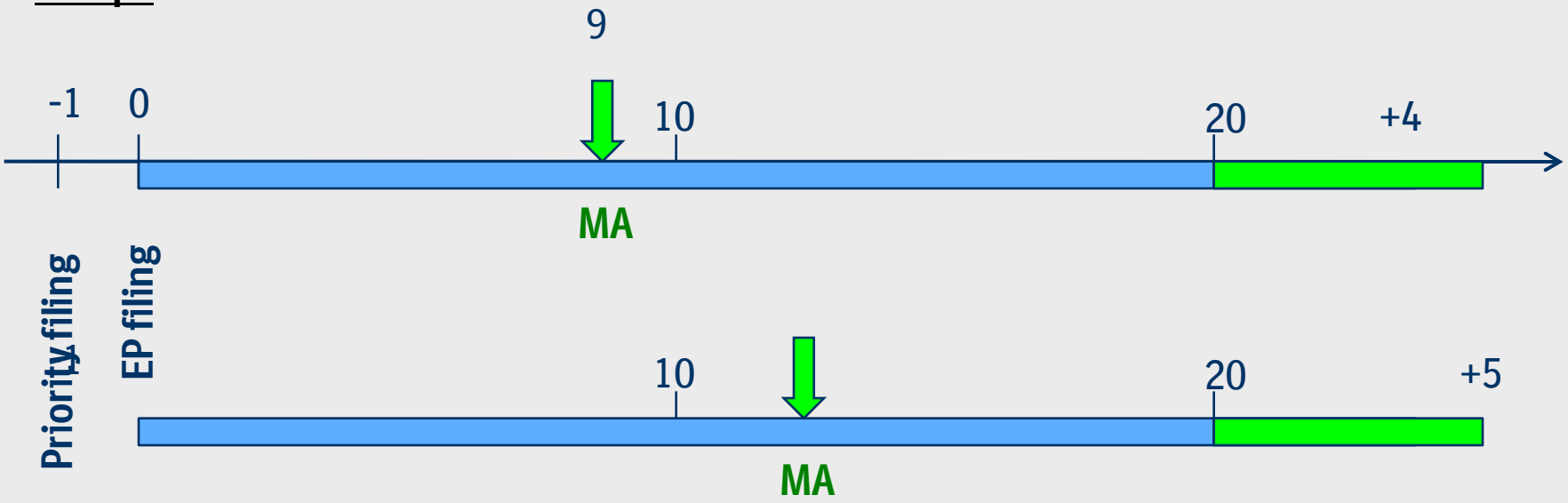
Europe



SPC = **Date of MA** – **Patent Filing date** – 5 years

(maximum 5y)

Ped. Regulation Europe - EG 1901/2006

The request for Marketing Authorisation (MAA) in Europe requires:

- a Pediatric Investigation Plan (PIP)
- which is to be negotiated and agreed with the European Medicines Agency (EMA),
- which is ethically justified,
- which concerns the pediatric population aged between birth and 18 years.

Rewards and incentives for the applicant:

Patent- / SPC protected medicinal product: option on a six-months SPC extension

From a development project to a market product – Patents, SPC & pediatric Extension

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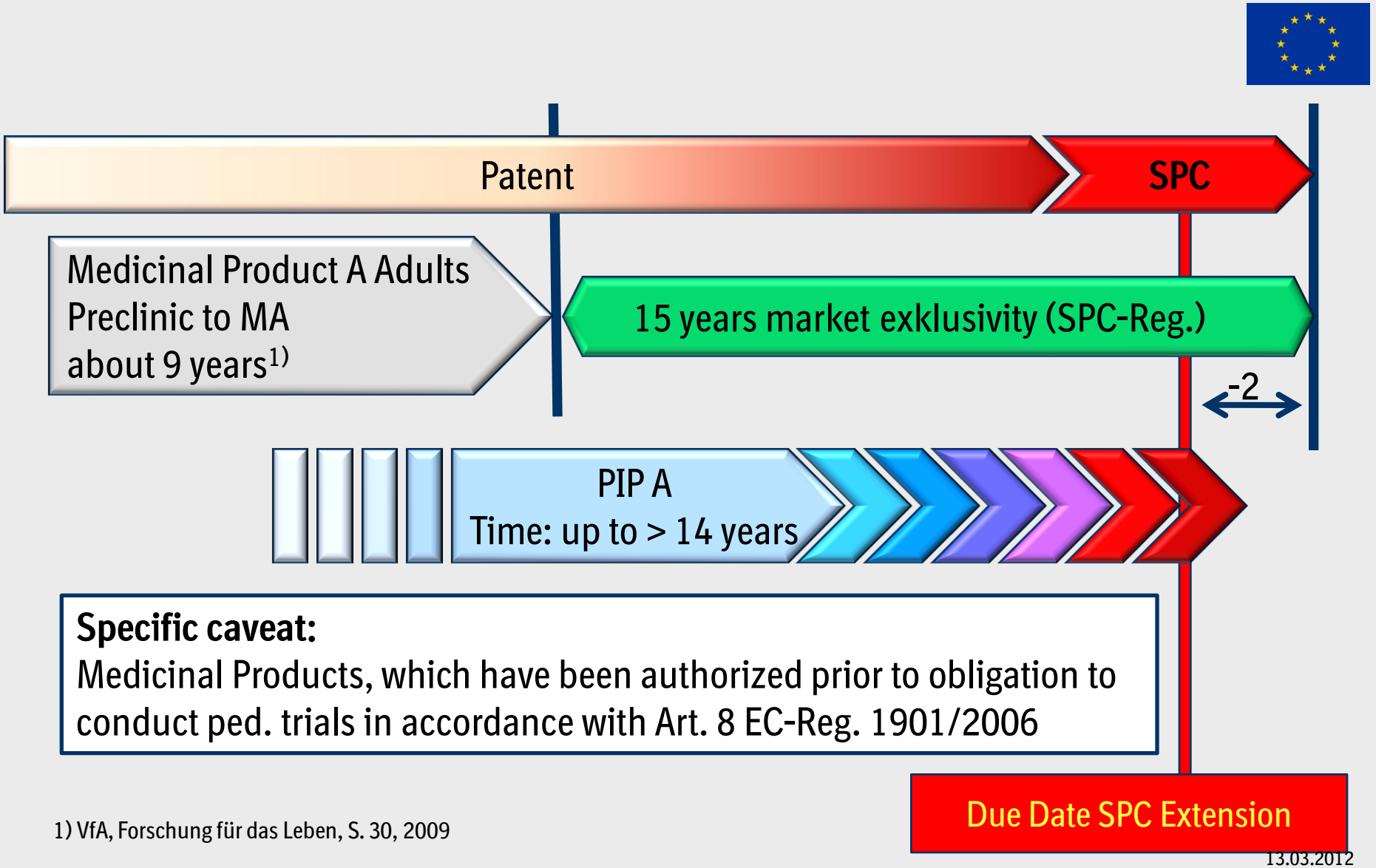

1) VfA, Forschung für das Leben, S. 30, 2009

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THANK YOU