



Rechtsfragen in der generischen Zulassung

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ANWALTSKANZLEI STRÄTER



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Arten von Zulassungsanträgen

- 1. Vollständig:** **Q** (Qualität)
W (Wirksamkeit)
U (Unbedenklichkeit)

trias – keine 4. Hürde
- 2. Generisch:** **Q + Bioäquivalenz**
→ **W + U (-)**
Bezugnahme auf Originator

→ nach Ablauf der Schutzfristen



Arten von Zulassungsanträgen

- 3. Gemischte Anträge:**
- vollständig
 - **Q**
 - **W + U:** Studien und Literatur
- 4. Hybride Anträge:**
- nicht vollständig
 - **Q + Bioäquivalenz**
 - **W + U:** eigene Studien + Verweis auf Originator

→ nach Ablauf der Schutzfristen

Arten von Zulassungsanträgen

5. **Bibliographisch:**
- **Q** + Bioäquivalenz
 - **W** und **U**: Literatur

Vor.: § 22 Abs. 3

Allgemeine medizinische Verwendung
(well established use – WEU –)

Beginn?

→ OVG Münster: mit Zulassung des OriginalAM

→ NTA Vol. 2a:

- auch vor Zulassung „medical use“ möglich
- notwendig, aber: extensive use
- klin. Studien etc. sind „less extensive use“

➔ vor Zulassung **less extensive use**



Arten von Zulassungsanträgen

5. Bibliographisch:

Welche Literatur – EuGH Scotia-Entscheidung
v. 05.10.1993, Rechtssache C-440/93

- vollständiger Nachweis
- Bioäquivalenz mit den Arzneimitteln, zu denen publiziert wurde?!
- Verwendung von Daten, die nach Informationsfreiheitsgesetzen erlangt wurden (**FOI-Daten**), z. B. summary bases of approval bzw. EPAR o.ä.

Streit: BfArM (+)

Gerichte voraussichtlich (-)

Umgehung der Schutzfristen!



Arten von Zulassungsanträgen

6. Biosimilars:

- generische Biotechs
(fast) vollständig
- **Q** große Bedeutung
- **W** und **U**: exercise of similarity
durch Klinik, umfassend, aber
nicht vollständig + Verweis auf
Originator



Arten von Zulassungsanträgen

7. Traditionell pflanzlich:

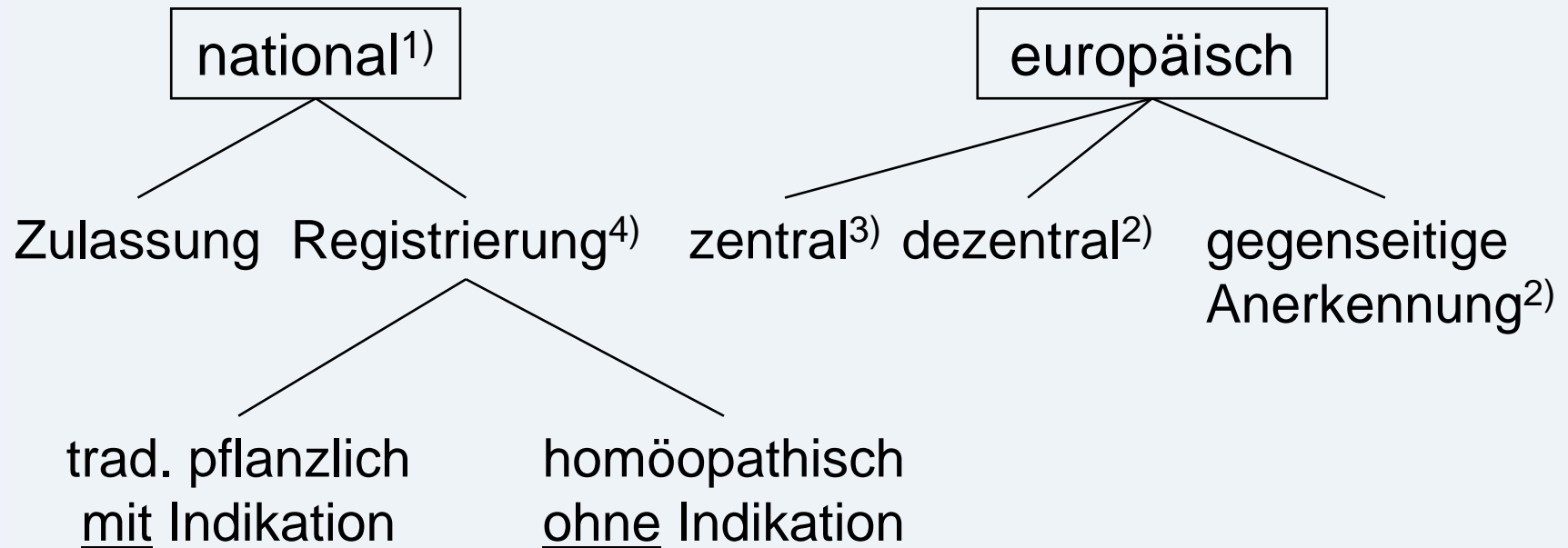
- Q → DAB
- W + U → Literatur
- **Registrierung**

8. Homöopathisch:

- Q → HAB
- W + U: Hahnemann + Monographien
- sonst nur **Registrierung**

Zulassungsverfahren

Unterlagenschutz – rechtl. Grundlagen



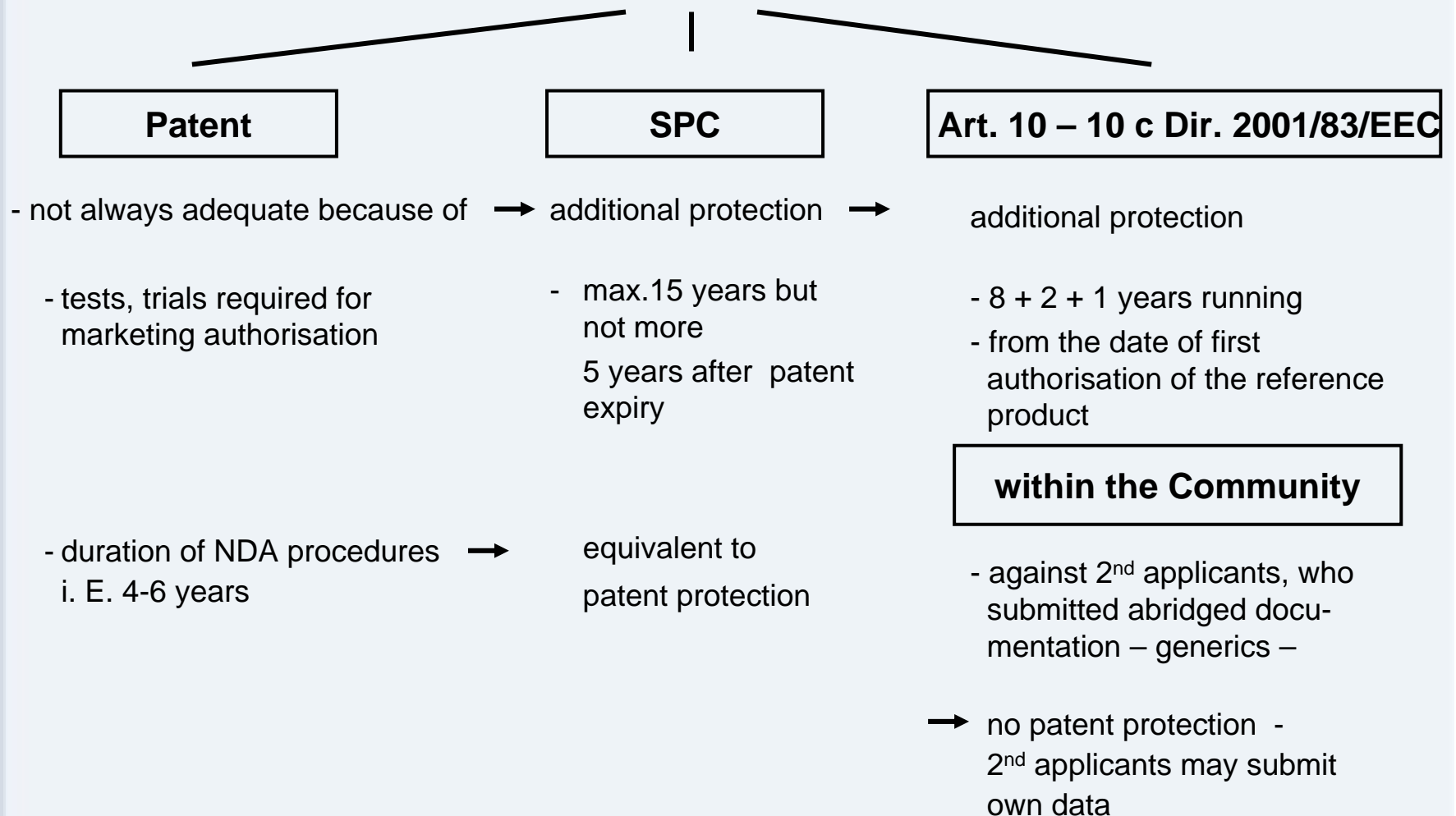
1) § 24 b AMG

2) Art. 10 RL 2001/83/EG

3) Art. 14 Abs. 11 Verordnung (EG) Nr. 726/2004

4) Keine rechtl. Bedeutung – aber Definition (DEV) bei Phytos

Protection of Pharmaceutical Innovation





Orphan Medicinal Products – OMP

EU Reg. 141/2000

MARKET Exclusivity Art. 8

- for 10 years no other application accepted by EU and MS for a

Similar Medicinal Product

- Reduction to 6 years if criteria are no longer met

- Exemptions:

- informed consent application
 - insufficient supply
 - a similar product is superior
- Def.: Art 3 EU-Reg. 847/2000

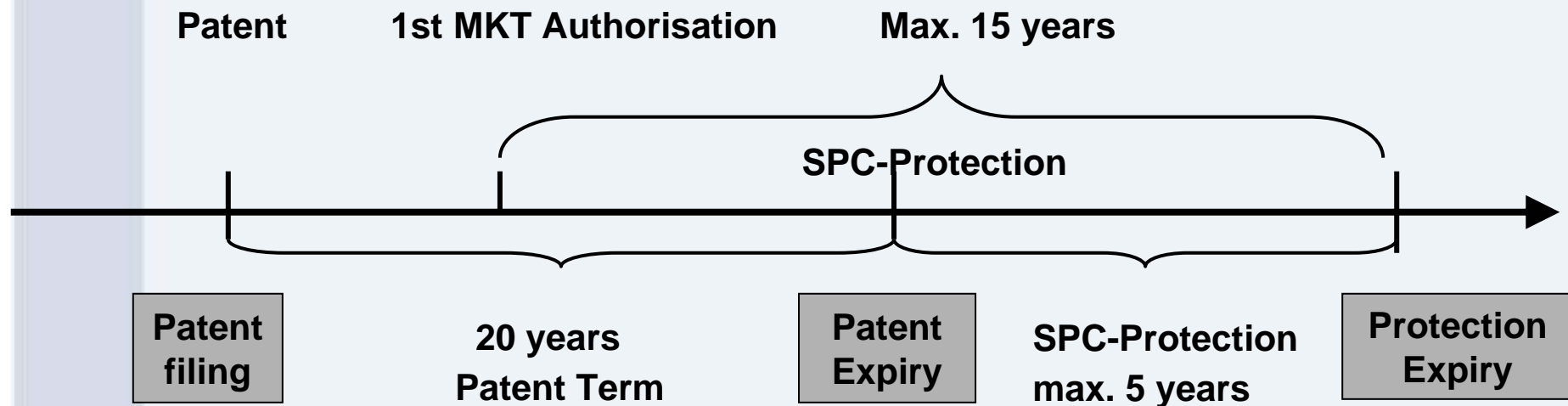
- Wide Definition of "Similar Medicinal Product"

≠ Essential Similarity in the case of Art. 4, No. 8, Lit a, iii

→ Def. : Art 3EU-Reg. 847/2000

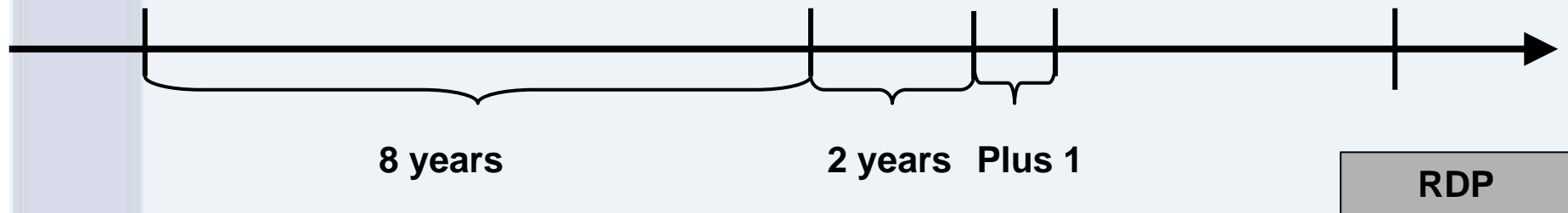
Efficient Protection against "Me Toos"

Supplementary Protection Certificate - SPC - EC Regulation → National Patent Law



Protection periods for regulatory data protection - RDP

1st MKT Authorisation
in the EU



Independent from patent!

Start of Protection Term

1st Authorisation
in UK

1st Authorisation
in France

1st Authorisation
in Germany

loss of protection

loss of protection

"within the
community..."

Years?
10?

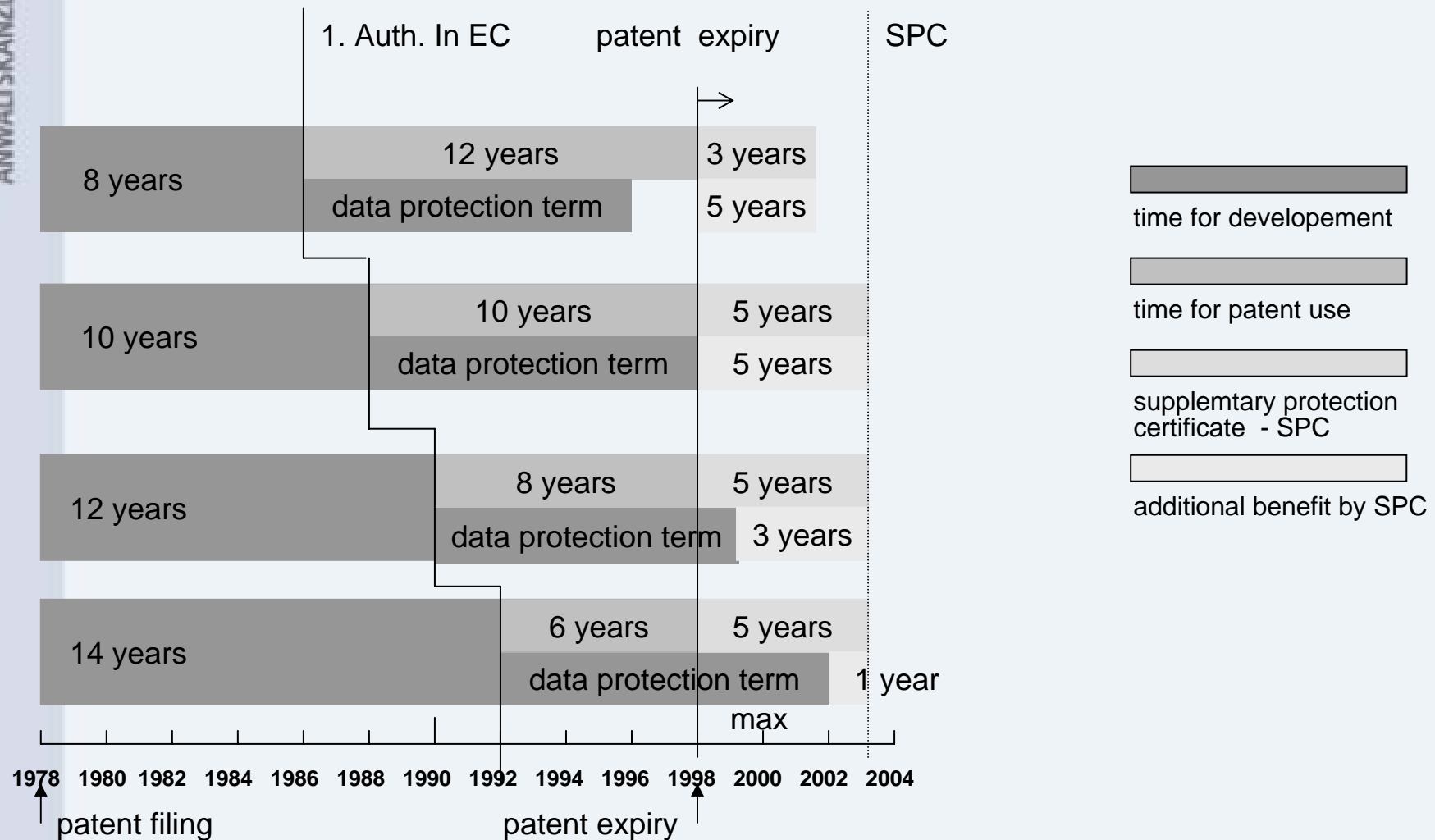
also in Member States other than
those in which the application is made

Period of exclusivity will be reduced
by the varying duration of NDA pro-
cedures

EC-wide uniform protection term

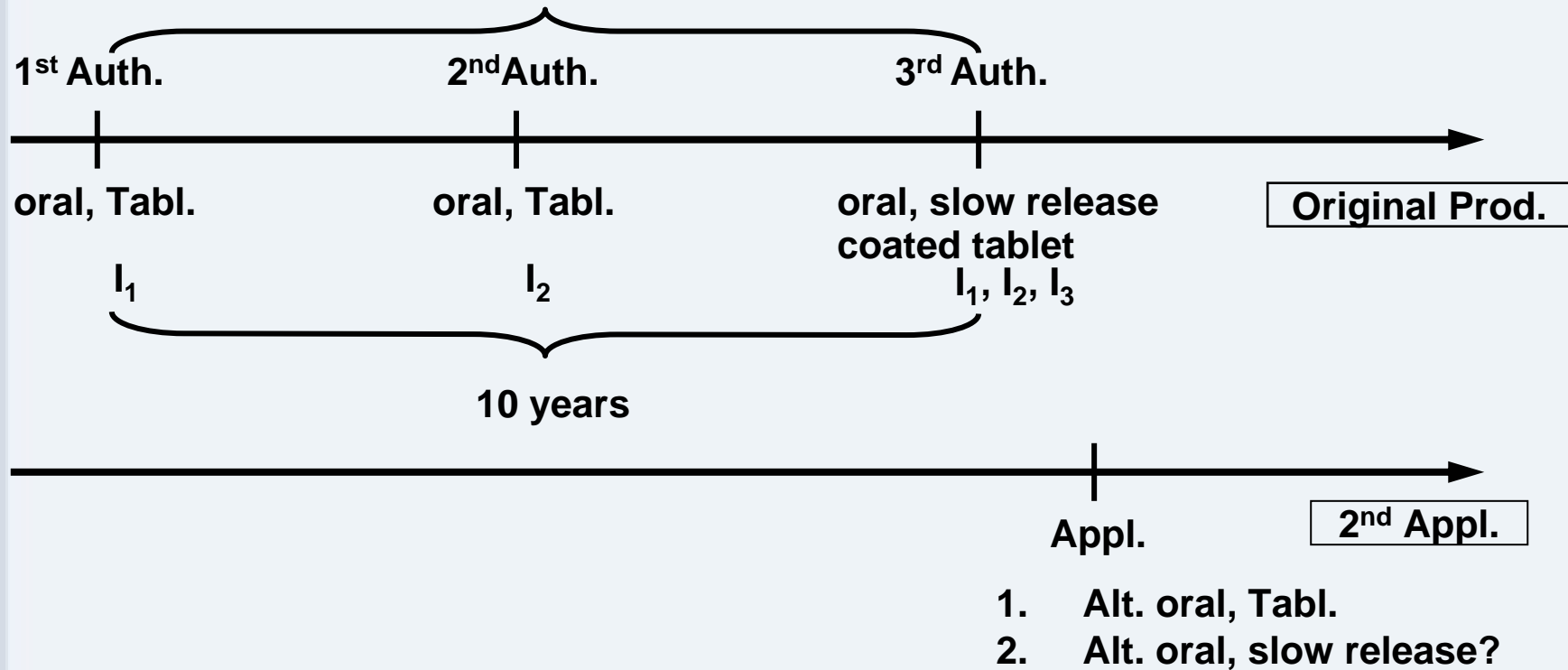
EC-wide coordination of the NDA
procedures is necessary

Influence of Data Protection Term according to Art. 10 Para 1(a) iii Dir 2001/83 EEC



ECJ – Essential Similarity Line Extensions of the Original MP

" Same Product" Art. 6 Global MA



New regulations for Line Extensions

Art. 6 para. 1 Reg. (EC) No. 726/2004

“When a medicinal product has been granted an initial marketing authorisation in accordance with the first subparagraph, any additional strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions shall also be granted an authorisation in accordance with the first subparagraph or be included in the initial marketing authorisation.

All these marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the application of Article 10 (1).”

→ **See also Annex II Variation Regulation**

§ 25 Abs. 9 S. 3 AMG



New Regulations for Line Extensions

Art. 6 (1) Reg., § 25 Abs. 9 S. 3 AMG

- All variations are one (1) authorisation within the meaning of Art. 10
- Period of Protection only once with initial authorisation
- No protection for line extensions
- exemption: PUMAs
- Special regulation for indications



Protection terms for new indications

Art. 10 (1) No. 4 Directive

Extension of the ban on placing on the market to 11 years for a new indication with significant clinical benefit within the first 8 years of the period of protection, i.e. after first marketing authorisation in the EU

→ 8 + 2 + 1

§ 24 b Abs. 1 S. 3 AMG

Cave: Extremely long transition periods for the 10/6 years protection terms (§ 141 Abs. 9 AMG)



Protection terms 6/10 years vs. 8+2+1

6/10 year terms apply for originator product for which MA was applied for before September 2005

→ for generic application the old 6/10 year terms apply until 2015



Generic – Reference Product

Art. 10 (2) a) + b)

Art. 10 (2) a) + b) Dir., § 24 b Abs. 1 S. 2 AMG

Definition:

- Reference medicinal product → Art. 6 !
Line extensions!
- Generic medicinal product Art. 10 para 2

§ 24 b Abs. 2 AMG

Types of Applications I

Dir. 2001/83/EC

Full stand alone application
Art. 8

Informed consent application
Art. 10 c

Generic application
Art. 10 para 1+2

Q
S
E



Reference with consent of MA

Q
Reference without consent after expiry of data protection



Generic Medicinal Product – Reference Medicinal Product

Art. 10 para. 2 b)

b) “‘Generic medicinal product’ shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.”

...~ ECJ an essential similiarity

§ 24 b Abs. 2 S. 1 AMG



Generic Medicinal Product – Reference Medicinal Product

Art. 10 para. 2 b)

“The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form.”

§ 24 b Abs. 2 S. 2, 3 und 4 AMG

→ Clopidogrel Hydrogen Sulfat vs. Besilat!

Bio Tech – Bio Similar

Art. 10 para. 4

Definition

- Bio-generic – bio-similar - bio-essential-similar ?

Presentation of own data in the case of differences in the production process “relating to these conditions”

- no others ?!

- Annex I EC Directive 2001/83 Part II 4)

→ “Comparability Exercise”

→ CHMP – General Guideline 437/04

→ product specific, insulin, EPO, somatropin

§ 24 b Abs. 5 AMG



Roche-Bolar clause

Art. 10 para. 5

“Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 to a generic medicinal product and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for those medicinal products.”

- **Product development, also pharmaceutical, possible during the patent term**
- **Buying-in of the raw materials**

§ 11 Abs. 2 b PatG

New indications of known substances

Art. 10 para. 4 a

“In addition to the provisions laid down in paragraph 1, where an application is made for a new indication for a well-established substance, a non-cumulative period of one year of data exclusivity shall be granted, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication.”

→ One year: non-cumulative but in addition to 8 + 2 + 1!

Benefit ?

Plus One Guideline EU-Com.

→ New stand alone application – restricted to the new indication, new name.

→ New product?! NTA 2 A Capt. I, S. 31 + 35 (-)

§ 24 b Abs. 6 AMG



Data Protection with Switch

Art. 74 a

Switch RX → OTC

“Where a change of classification of a medicinal product has been authorised on the basis of significant pre-clinical tests and clinical trials, the competent authority shall not refer to the results of those tests or trials when examining an application by another applicant for or holder of marketing authorisation for a change of classification of the same substance for one year after the initial change was authorised.”

→ **One year protection against referencing**

Problem: Implementation in Germany because duty to prescribe regulated by ordinance

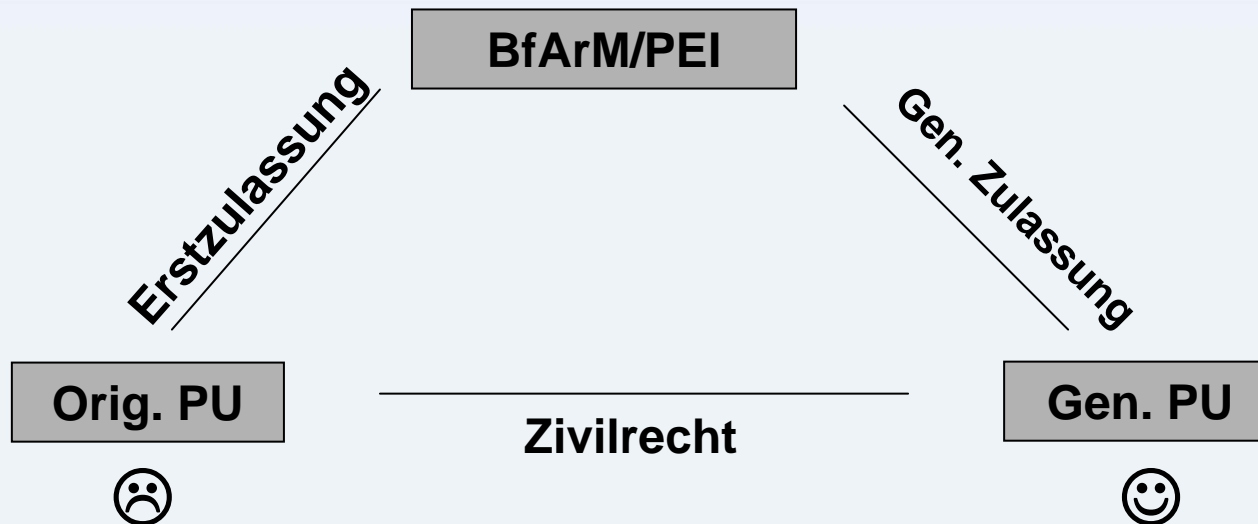
§ 48 Abs. 3 S. 3 AMG



Conclusion:

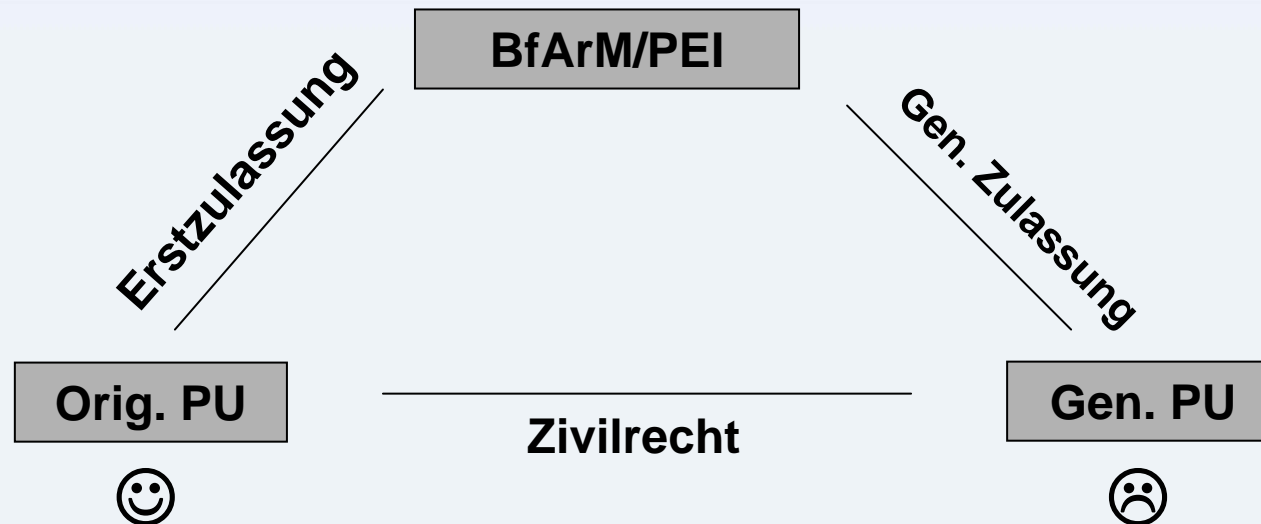
- Uniform periods in the EU **8 + 2 + 1**
- Facilitation of the MR procedures
- Product development possible during the term of the patent!
- No protection for line extensions
- Limited data protection with Switch → OTC

Rechtsbehelfe des Originators gegen BOB



- 1) **Drittwiderspruch § 80 a VwGO**
→ **aufschiebende Wirkung § 80 I VwGO**
Durchsetzung im Markt?
- 2) **Bestätigung BfArM oder § 80 Abs. 5 VwGO analog auf Feststellung**

Rechtsbehelfe des Originators **gegen BOB**



- **Drittwiderspruch mit bestätigter aufschiebender Wirkung**
- **Gen. PU → Antrag auf Sofortvollzug § 80 Abs. 2 Nr. 4 VwGO**
- **Orig. PU → § 80 Abs. 5 VwGO auf Wiederherstellung der aufschiebenden Wirkung**

VG Köln – ca. 3 Monate

Beschluss – Beschwerde OVG NRW/MS

Rechtsbehelfe des Originators gegen Gen. PU



WettbewerbsR - UWG

→ **Unterlassen des Vertriebs wegen fehlender Zulassung**

e. A.

**erfolgreich, wenn BOB oder VG/OVG
die aufschiebende Wirkung bestätigen!**

§ 945 ZPO

**Schadensersatz (-) wenn e. A. nur
für die Dauer der aufschiebenden Wirkung**



Vielen Dank für Ihre Aufmerksamkeit!

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