Panel Discussion 4:
BALANCING DATA AVAILABILITY AND NEED TO KNOW;
Data protection, availability of information to researchers and best practices
### Types of Exclusivity in Pharmaceutical Industry

<table>
<thead>
<tr>
<th>Type of Exclusivity</th>
<th>Details / Examples</th>
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</table>
| **Regulatory Exclusivity** | - data protection  
- market exclusivity  
- re-examination periods |
| **Patent Exclusivity** | - SPC / PTR (PTE)  
- Ped. exclusivity |
| **Know How Exclusivity** | depends on technology / Catapress TTS / Respimat® |
| **Specific Market Factors** | e.g. not attractive from profit side?  
// Combivent® (CFC) USA? |

Concerns originator exclusivity periods with regard to a third party’s generic marketing authorization application referencing the same.

Technical IP: Only available for technical inventions.

The patent allows its owner to forbid another persons to use his invention.
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
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

Reg. Exclusivity period Europe: Example NCE

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

+ 1 y ME

Ref. MA

8 y DE

2 y ME

EMA Review possible

GxMA

13.03.2012
Regulatory Exclusivity

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](http://www.fda.gov/default.htm)

Dr. Elke Simon - CONFIDENTIAL
### Terms of Regulatory Protection

<table>
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<tr>
<th>Region</th>
<th>NMEs</th>
<th>FDA Review Period</th>
<th>Re-examination</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Europe</strong></td>
<td>( \sum_{\text{max}} 11 \text{ y NMEs} )</td>
<td>8 y DE + 2 y ME + 1 y ME</td>
<td><strong>re-examination</strong> after 8 y (10 y if pediatric data provided), exact time is set by Health Authority</td>
</tr>
<tr>
<td><strong>USA</strong></td>
<td>( \sum_{\text{max}} 5.5 \text{ y NCEs} )</td>
<td>NCE: 5y DE, opt. + 0.5 PE ANDA: 4 y DE + 1 y ME; opt. + PE that adds on 4 y term</td>
<td></td>
</tr>
<tr>
<td><strong>Japan</strong></td>
<td>( \sum_{\text{max}} 8 - 10 \text{ y NMEs} )</td>
<td><em>re-examination: Health Authority „revisits“ the review process</em></td>
<td></td>
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*Possible patent litigation and 30 months stay not considered*

*FDA review period not considered*
The missing link - Europe

**Patent Letter**

I claim:

A compound selected from the group of

... and the pharmaceutically acceptable salts thereof.

**Supplemental Protection Certificate (SPC)**

I claim:

**INN** and the pharmaceutically acceptable salts thereof.

**Market Authorization**

for to market **INN**

as a medicinal product.
• 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
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

Europe

SPC = Date of MA - Patent Filing date - 5 years

(maximum 5y)
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

Medicinal Product A Adults Preclinic to MA about 9 years¹)

15 years market exclusivity (SPC-Reg.)

PIP A
Time: up to > 14 years

Specific caveat:
Medicinal Products, which have been authorized prior to obligation to conduct ped. trials in accordance with Art. 8 EC-Reg. 1901/2006

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