



# How to prepare for and navigate the IP Due Diligence

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Dr. Jörk Zwicker – ZSP Patentanwälte PartG mbB

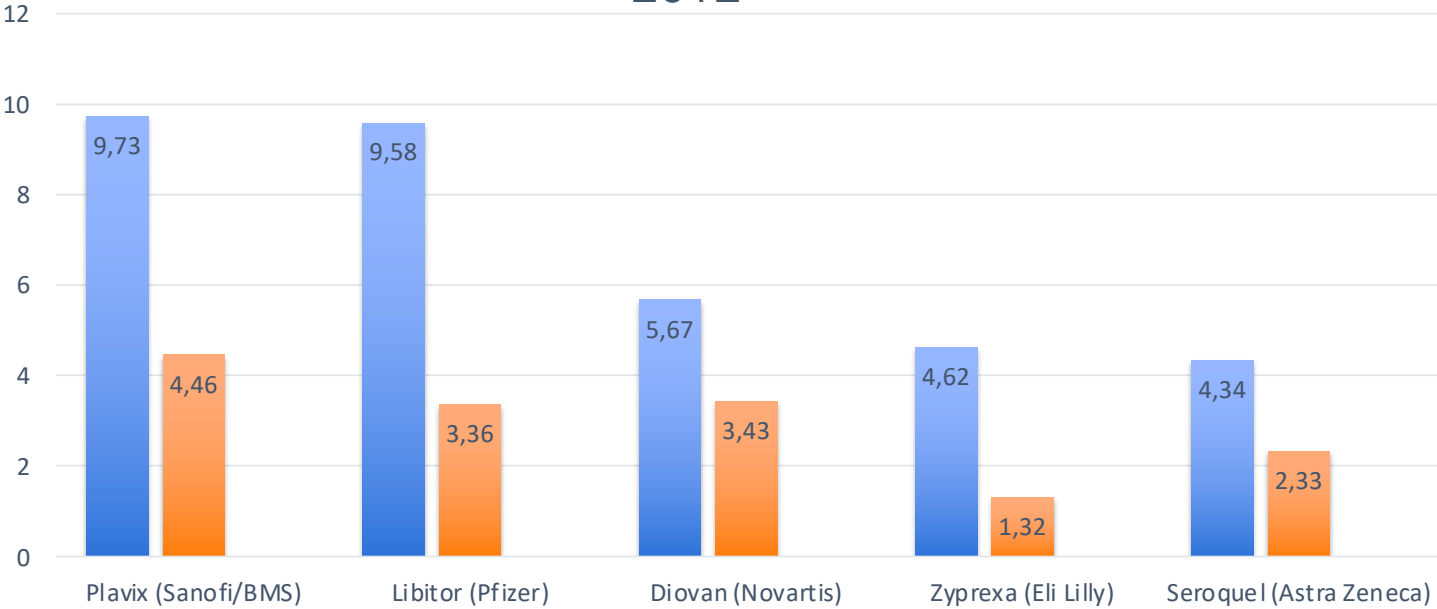
# Overview of the IP Due Diligence Process

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- What is the purpose of an IP Due Diligence
- Aspects evaluated in an IP Due Diligence
  - Patent portfolio of Company and its Relevance for Companies product
  - Ownership of Companies patent portfolio
  - Third Party Rights and their relevance for Companies product (FTO)
- How to prepare for the IP Due Diligence Process

# Competitive Value of Patents

Net Sales in Billions of \$ prior to and after the End of the patent term in the period of 2011 to 2012



# The purpose of an IP Due Diligence

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Due Diligence = „gebührende Sorgfalt“

→ The process by which an investor assesses its investment target

## IP Due Diligence

- Patents are tools to gain a competitive advantage over third parties
- Assesses competitive advantage of company for its products
- Assesses third parties competitive advantage for companies products

# Patent Portfolio of Company

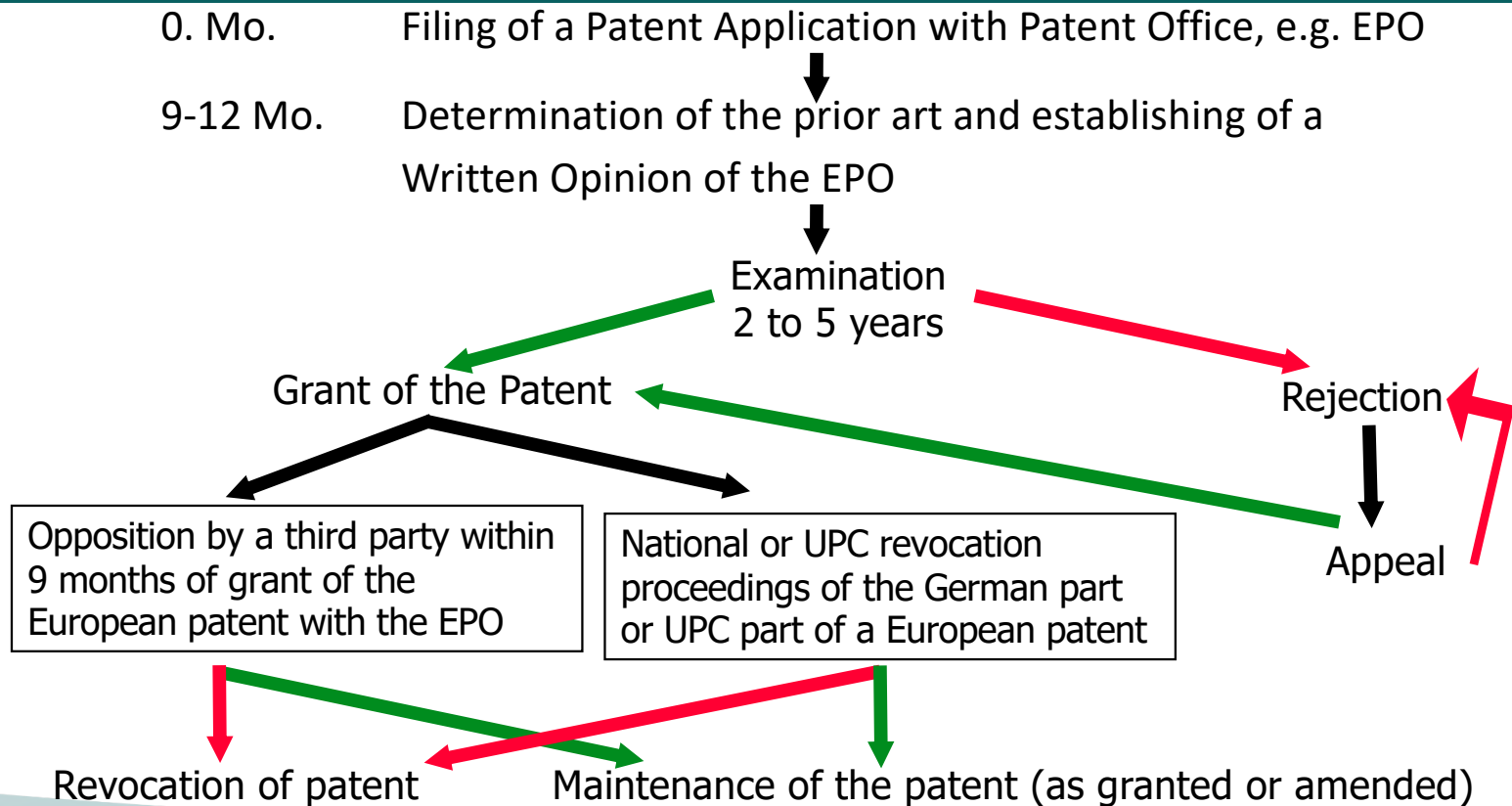
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Patent is an intellectual property (IP) right protecting a technical invention

Effect of a Patent:

- Provides a right to exclude (NOT a right to use!)
- Is absolute, i.e. has an effect in relation to every commercial activity
- For a limited time - generally 20 years from the filing date but can be extended for patents for pharmaceutical products by up to 5 or 5.5 years
- Territorial limitation, i.e. the patent has only effect national or regionally in the area for which it is granted
- Provides the public with knowledge of the invention 18 months after the patent application is filed

# Patent Portfolio of Company – Grant Process



# Patent Portfolio of Company - Claims are key

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1. A monoclonal antibody or fragment thereof that binds to human PCSK9 and is neutralizing in that an excess of said antibody or fragment thereof is capable of reducing the quantity of PCSK9 bound to LDLR in an *in vitro* competitive binding assay, wherein said monoclonal antibody or fragment thereof competes for binding to PCSK9 with
  - (a) an antibody comprising a heavy chain variable region of the amino acid sequence in SEQ ID NO: 49; and a light chain variable region of the amino acid sequence in SEQ ID NO: 23; or
  - (b) an antibody comprising a heavy chain variable region of the amino acid sequence in SEQ ID NO: 67; and a light chain variable region of the amino acid sequence in SEQ ID NO: 12.

*„The scope of protection is determined by the content of the patent claim“ (§ 14 , Sentence 1 PatG)*

- The scope of the claim determines the rights of the patent owner, i.e. it determines the breadth of the exclusion rights
- The scope of the claim is determined by national infringement courts or the UPC
- The scope of the claim is determined through the eyes of the skilled person in light of the description and figures (§ 14 Abs. 2 PatG)

# Patent Portfolio of Company - Product Claims

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Substances and mixtures thereof, devices (machines), circuits and arrangements produced by human activities

- **Substance protection**

- Substances and mixtures thereof are patentable as a product
- In particular: drug (active compound, active compound in admixture with non-active ingredients → galenic products)

- **Scope of Protection of a Product Claim**

Exclusion rights cover all uses of the product, including making, possessing, using, offering for sale, selling, and importing



# Patent Portfolio of Company - Purpose Limited Substance Protection

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- Protection for a known substance for use in therapy (1. Medical Use)

Claim format: *"Substance X for use in therapy"*

- Protection for a known substance for use in therapy of a particular disease (2. Medical Use)

Claim format: *"Substance X for use in therapy of disease Y"*

# Patent Portfolio of Company - Purpose Limited Substance Protection

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- **Scope of Protection of a Purpose Limited Substance Claim**
  - Exclusion rights cover the evident preparation for the indicated purpose  
→ “Label protection” covers the generic producer
  - Exclusion rights cover the offering for sale for the indicated purpose  
→ Covers the doctor prescribing a drug and a pharmacist dispensing the drug for the indicated purpose

# Patent Portfolio of Company - Method Claims

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All types of activities which generally use some tangible product for carrying out the method

## **Production Method**

Methods to produce a product, i.e. substance or device

## **Scope of Protection of a Production Method Claim**

Exclusion rights cover the carrying out of each step of the claimed method

Exclusion rights cover the “immediate” product of the production method

# Patent Portfolio of Company - Method Claims

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## **Working Method**

- Computer implemented method (software patent)
- Diagnostic method
- Screening method
- Selection method

## **Scope of Protection of a Working Method Claim**

- Exclusion rights cover the carrying out of each step of the claimed method

# Patent Portfolio of Company – Patent Portfolio Strategy

## Case Study C5A specific mAb (Inflarx)

Product claims covering C5a specific antibodies:

- (i) Functionally defined by the epitope bound by the antibodies ;
- (ii) Structurally defined by the six CDR sequences
- (iii) Structurally defined by the full V<sub>H</sub> and V<sub>L</sub> sequences

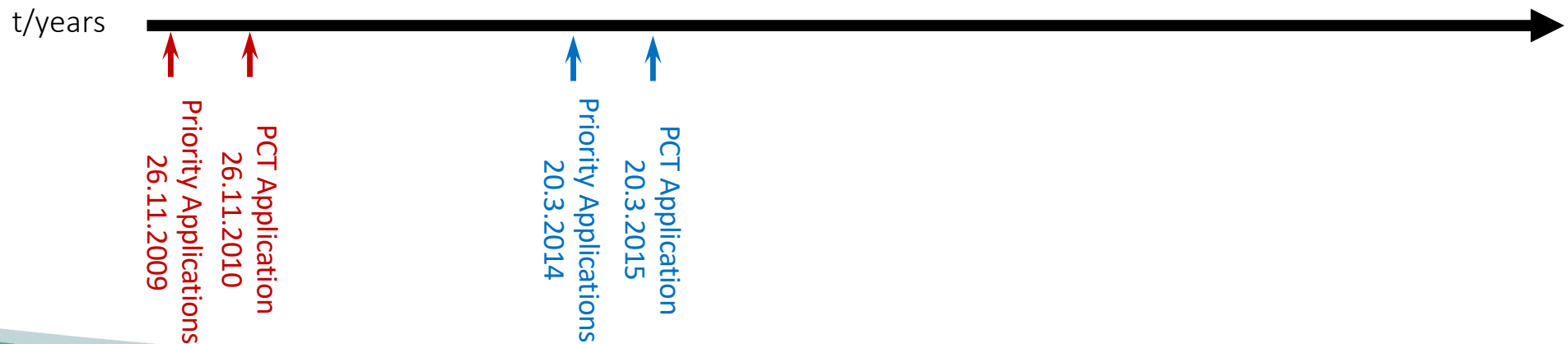


# Patent Portfolio of Company – Patent Portfolio Strategy

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Case Study C5A specific mAb (Inflarx)

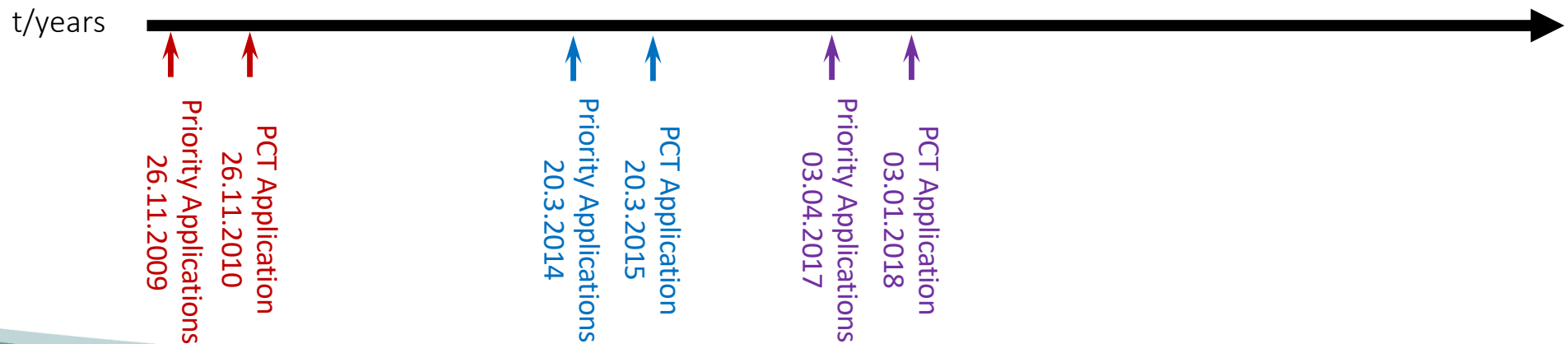
Second medical use claims covering use of C5a specific antibodies in the treatment of viral pneumonia by reducing the viral load



# Patent Portfolio of Company – Patent Portfolio Strategy

Case Study C5A specific mAb (Inflarx)

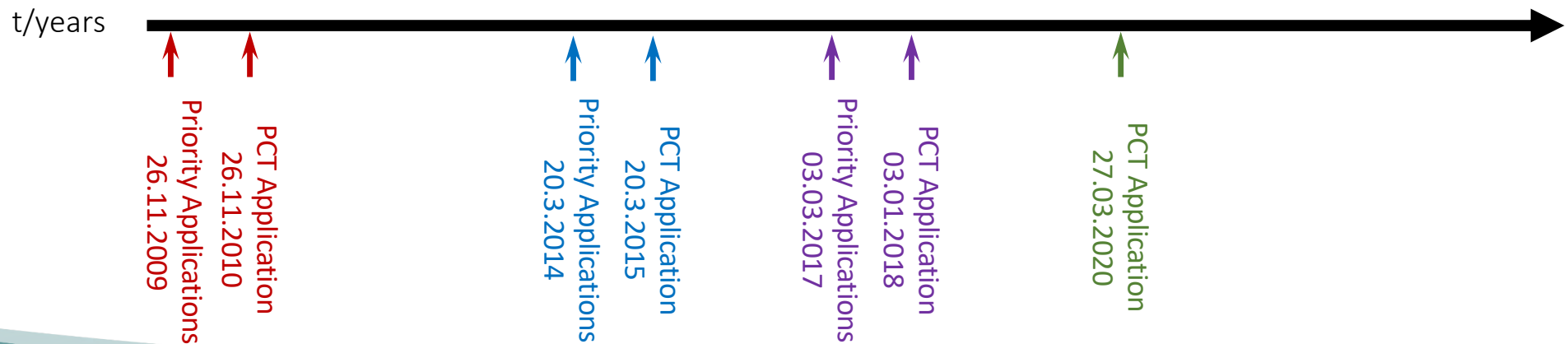
Second medical use claims covering use of C5a specific antibodies in the treatment of Hidradenitis suppurativa



# Patent Portfolio of Company – Patent Portfolio Strategy

Case Study C5A specific mAb (Inflarx)

Second medical use claims covering use of C5a specific antibodies in the treatment of SARS-COV2 induced viral pneumonia

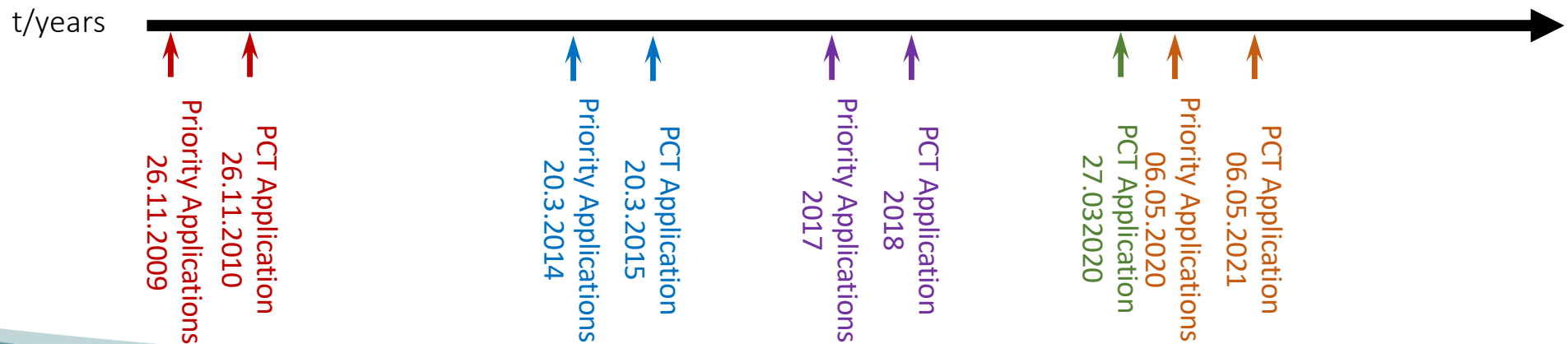




# Patent Portfolio of Company – Patent Portfolio Strategy

Case Study C5A specific mAb (Inflarx)

Product claims covering humanized C5a specific antibodies structurally defined by the full VH and VL sequences



# Patent Portfolio of Company – Assessment during IP Due Diligence

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## **Assess patentable/valid scope of the claims of Companies Patents**

- The assessment is based on the prior art already identified by the various patent offices
- The assessment is based on independent searches of prior art

## **Assess whether the patentable scope of the claims covers Companies Product(s)**

- Products change during the development process
- The characterization of the clinical indication changes during the process of market authorization

# Patent Portfolio of Company – Assessment during IP Due Diligence

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## **Assess patent life cycle strategy**

- Product patents
- Second medical use patents
- Second generation product patents
- Formulation patents
- Administration regimen patents

## **Assess SPC/PTE strategy**

# Patent Portfolio of Company – Ownership of Companies Patent Portfolio

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The Inventor is owner of the Patent

But: Who is an inventor?

Every person who contributed to the solution of the invention not merely by routine activities but by some creative contribution. The individual contributions of co-inventors must not involve inventive activity.

# Patent Portfolio of Company – Ownership of Companies Patent Portfolio

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Initially the inventor is the owner of the invention. There often is an obligation on the inventor to assign through:

1. Contractual obligation, e.g. „Directors Employment Contract“
  - Only applicable if the inventor is not covered by the German Employee Inventors Act (ArbErfG). Such contracts are void, if they are concluded with employee inventors prior to notification of the invention
2. German Employee Inventions Act (ArbErfG):
  - Applicable to all employees, including employees at the university, e.g. university professors
  - **Not** applicable to representatives of legal persons (AG or GmbH) or personally liable directors of a KG

# Patent Portfolio of Company – Ownership of Companies Patent Portfolio

## **Obligation of the Employee:**

- Disclosure of the Invention in writing or in text form

## **Automatic Claim of the Invention**

Exception: Employer releases the invention within 4 months

## **Obligations of the Employer:**

- Submission of a patent application without delay
- „Without delay“ includes the time required for evaluation of the invention, carrying out a search, decision making process and drafting a patent application → typically 2 to 3 months
- Employee Inventor Compensation

## **Rights of the Employer:**

- Submission of Patent Applications abroad
- Abandoning national/international applications

## **Obligations of the Employer:**

- Information about the progress of the patent application
- Release of the invention for (and offering) international application

# Patent Portfolio of Company – Ownership of Companies Patent Portfolio

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## **Assess determination of inventorship**

- Has the company a procedure in place to determine who should be named as (co)inventor of a new invention?
- How was inventorship determined for Companies Patents?

## **Assess transfer of rights from inventor to Company**

- Has each inventor transferred his/her rights in the invention to the Company?
- If an inventor has not transferred its rights as of yet, is there an obligation to transfer?
- If an inventor is obligated to transfer rights in his/her invention to a third party, i.e. a University, is an agreement in place granting Company rights in such inventions?

# How to Prepare for the IP Due Diligence - Companies Patent Portfolio

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## **Prepare for patentability/validity questions**

- Analyze relevance of prior art identified by the patent office(s)
- Determine a prosecution/defense strategy
- Determine a patent life cycle management strategy
- Determine a SPC/PTE strategy (during clinical trials)

## **Prepare for questions regarding ownership**

- Establish a process for handling employee inventions according to the ArbErfG
- Ascertain that an invention disclosure is obtained for each invention for which a patent is filed;
- Provide evidence of claim of employee inventions
- Provide evidence of assignment by all inventors that are not employees under ArbErfG or employed by a third party
- For inventors that are both employees of a third party, e.g. University, and Company conclude “Nebentätigkeitsgenehmigungen” which attribute rights in inventions made at the Company to the Company



# Third Party Rights - Freedom to Operate Analysis (FTO)

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## **Analysis of Product/Device/Method of Company**

- Determine structure and function of product/device
- Identification of critical features of a a product or method
- Determine intended use/indication, e.g. indications label language

## **Search for Third Party Patents with claims covering Product/Device/Method**

- Search for structures of small chemical molecules in, e.g. in Marpat
- Search for amino acid sequences in Chemical Abstracts patented sequence databanks
- Search with key-word searches in various patent databanks, e.g. in Derwent, Chemical Abstracts, full text patent databanks.

# Third Party Rights – Relevant Claims

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- Determine the features of the claims
  - Determine the meaning of the features
  - Determine the literal scope of protection
  - Determine the equivalent scope of protection
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- ➔ List of Patent Applications with potentially relevant claims
  - ➔ List of Patents with potentially relevant claims
  - ➔ List of Patents with relevant claims

# How to Prepare for the IP Due Diligence - FTO questions

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## **Identify potentially relevant patents and patent applications and prepare and execute strategy for each one:**

- Establish monitoring of patent applications
- Develop an invalidity strategy ==> Opposition, nullity suits, identify prior art and keep your “powder dry”, etc.
- File or prepare to file third party observations to prevent patenting
- Contact patentee to determine licensing opportunities (including presenting them with your invalidity strategy)
- Develop an engineering around strategy



## **Dr. Jörk Zwicker**

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Patentanwälte | PartG mbB  
Hansastr. 32  
80686 Munich, Germany

T +49 89 998 479 6  
F +49 89 998 479 79  
E [zwicker@zsp-ip.de](mailto:zwicker@zsp-ip.de)