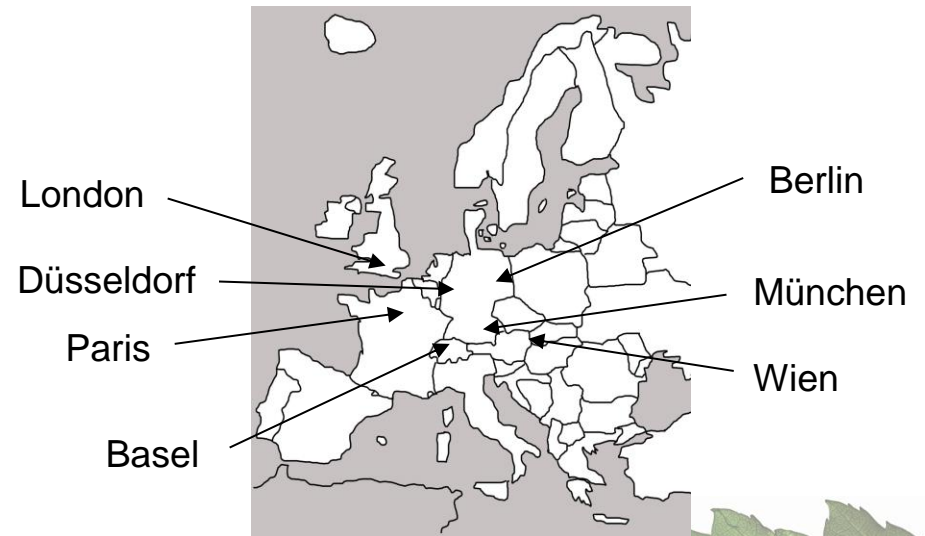
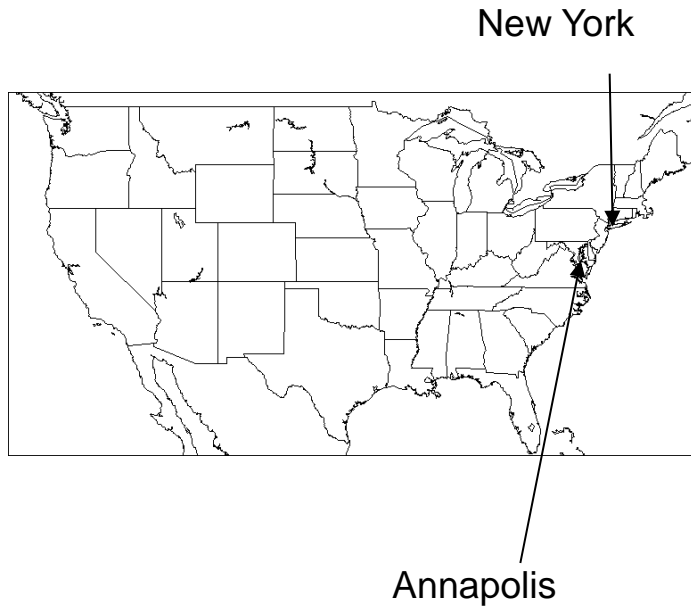


# Innovative Business Planning around Intellectual Property (IP) – with a specific focus on Life Science Companies

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## 24IP Law Group



## Sebastian Tegethoff – Vita

- Diploma Biology, Göttingen University
  - Developmental Biology
- Ph.D. Molecular Biology/Immunology Max-Delbrück-Centrum Berlin
  - Characterisation NF- $\kappa$ B activating kinase complex
- German Patent Attorney
- European Trademark and Design Attorney
- European Patent Attorney
- Lecturer and Coordinator Beuth UAS Berlin on Patent Law and Law on Employees' Inventions since 2007
- Lecturer UAS Hamm-Lippstadt on “Strategically IP Management”, 2015
- Lecturer European Patent Academy of EPO

## What is so special about IP in Life sciences?

„beginning with the end in mind“



→ Avoid to be „off-patent“ after grant of your patent



## What is so special about IP in Life sciences?

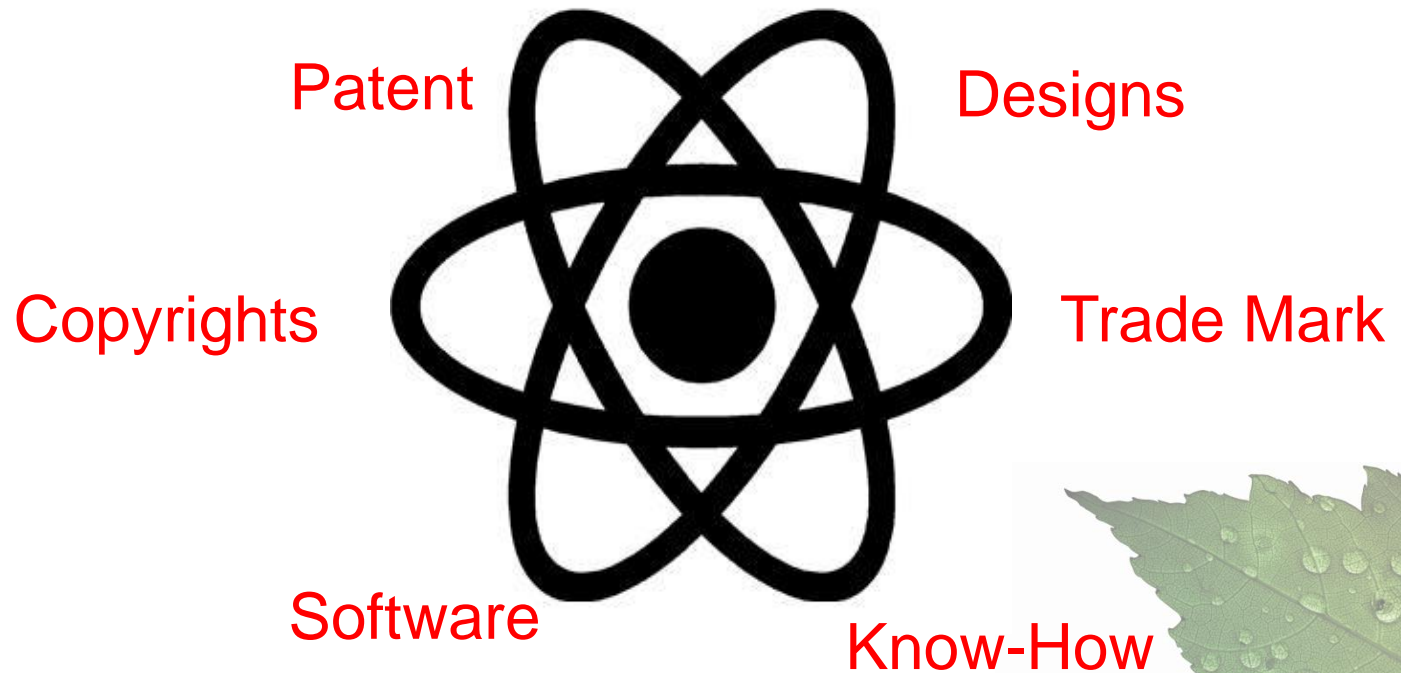
„dancing between the raindrops“



→ Prior art is a jungle!



## What do we mean by Intellectual Property?





## Building an IP Portfolio



## Building an IP Portfolio

It's all there – but has no structure!





## Building an IP Portfolio

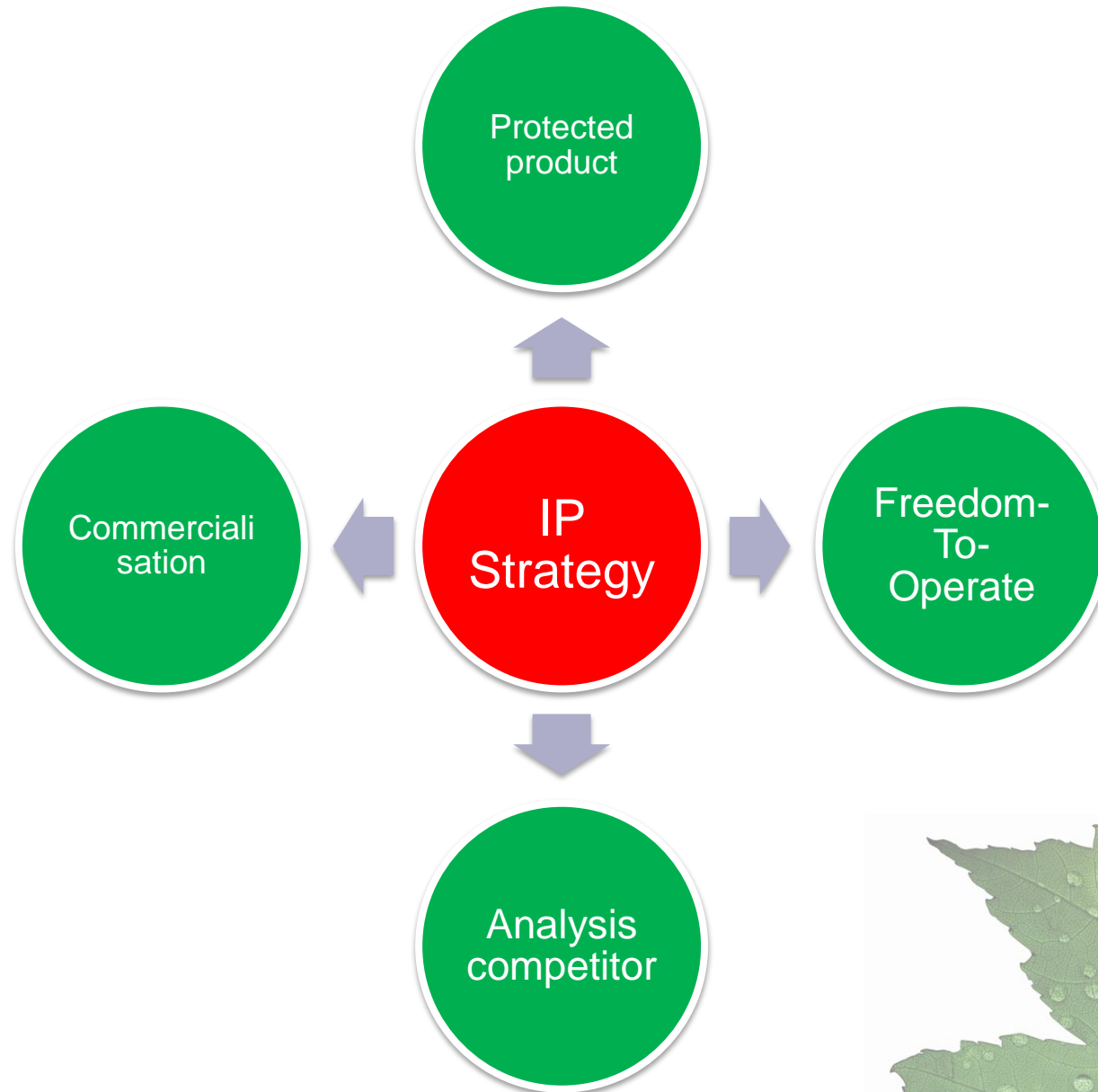
It's all there – and you can use it!



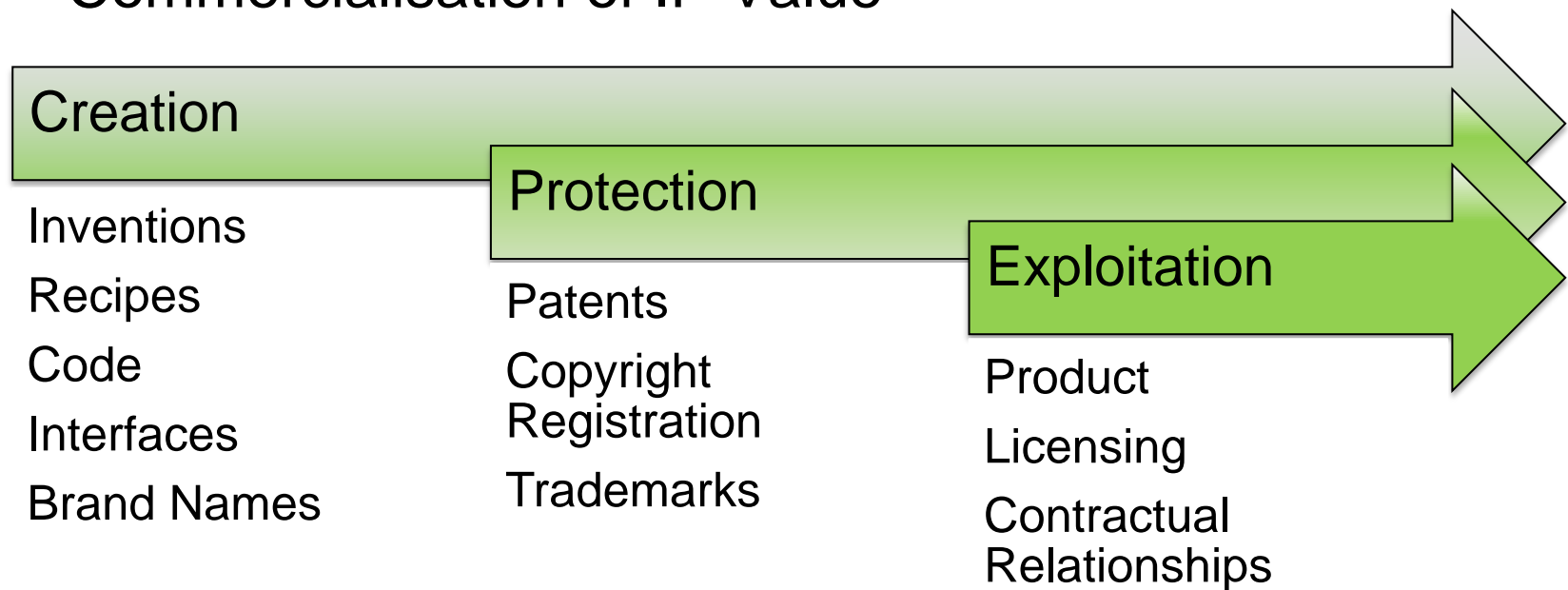
In IP, big is not always beautiful

Remember the death Star:  
Efficacy kills sheer size.

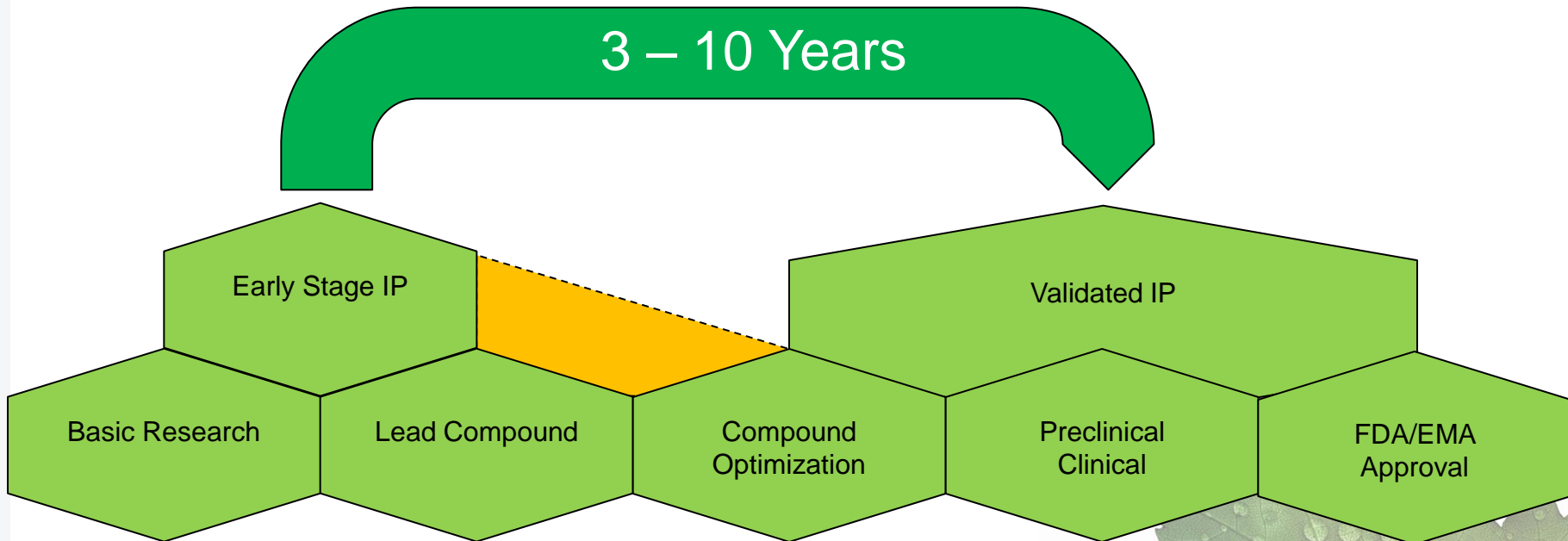




## Commercialisation of IP Value



## IP and Drug Development



## Setting up an IP strategy



- Several countries in Europe (France, Luxembourg, Netherlands, Belgium, etc.) use the European Patent Office as the Search Authority for national patent applications.
- The applicant receives a European-style search report
- It is possible to anticipate a major part of the European examination procedure.
- The European-style search enables the applicant to identify any relevant prior art and to adapt the claims and/or description to the European requirements within the first year after filing the initial application (priority application).
- A subsequent European application will benefit from the prior search results, because the same Examiner will be responsible



## A national route to the EPO Case study: Luxembourg



- An example for a National-to-European strategy is to file first a national application in Luxembourg.
- The Luxembourg application can be filed in French, German or English (claims in German or French).
- The cost of the European-style search report is for Luxembourg is very low at only €250 Euros.
- The same Examiner will be responsible for a European or International application
- Clearing all objections and filing directly a European application will speed up grant
- Search fee of subsequently filed European application will be mainly refunded

## EXAMPLE

### Starting Point

→ Discovery that inhibition of receptor has beneficial effects

Note: Discovery is not protectable by patents!

### Invention

→ Drug Discovery of receptor inhibitors by high through put screen

→ Identification of lead compounds



## EXAMPLE

### IP strategy

- Search for lead compound(s)
- Search for literature supporting use (rationale)
- Involve chemist for optimization
- Data available supporting rationale?



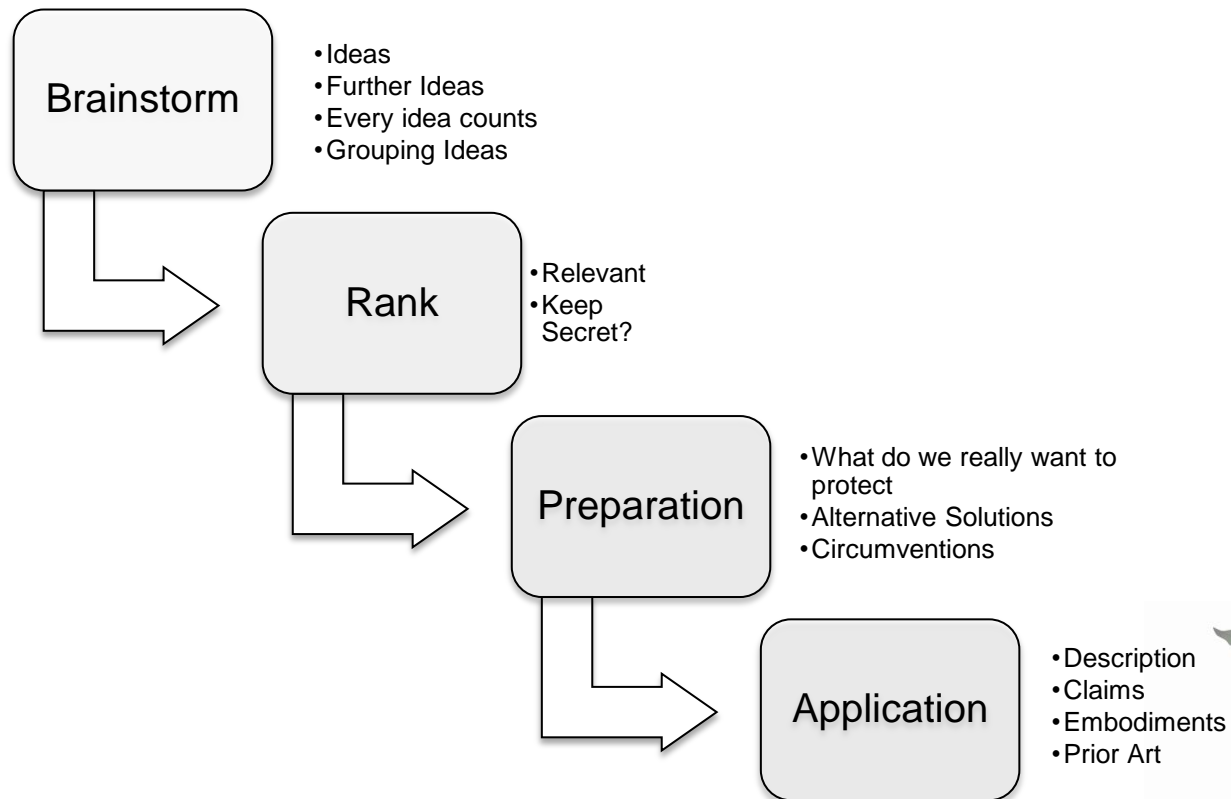
## EXAMPLE

### Filing strategy

- First filing for obtaining official search report (LU; UK)
- Ready for subsequent filings: data present?
- **If not:** Withdraw first filing and re-file for obtaining new priority
  - optimization and
  - search for investors
- File PCT for obtaining additional time for
  - optimization and
  - search for investors
- Data available, term sheets signed: Speed-up prosecution



## Harvesting Process for protection around core IP



# Harvesting und Rating

Harvesting und Rating							(Months)
	5=Potential to enable an (de facto) industry standard 1=Unique Application (point solution)	5=great 1= simple	5=Highly Visible 1=totally invisible	5=not easy (broad claims possible) 1= Many other solutions (narrow claims)	5=lots of other applications 1=restricted to field	5=not a lot of art (broad claims possible) 1=lots of relevant art (narrow claims)	
Summary of Ideas	Essential to business	Technology	Visible to Competitor	Easy to work around	Application in other field	Prior Art	Time to Release (Generally available)





## Patents - Art 52 EPC

- New
- Inventive
- Commercially Applicable
- Not excluded from patent protection



## Avoid the therapy, surgery, diagnostic trap - in Europe

### Article 53 EPC

European patents shall not be granted in respect of:

(c) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body;

this provision shall not apply to products, in particular substances or compositions, for use in any of these methods



## Avoid the therapy, surgery, diagnostic trap - in Europe

- European method exceptions are confined to surgery / therapy / diagnostic methods

### Not a method of treatment:

- treatment of a sheep in order to promote growth, to improve the quality of mutton or to increase the yield of wool
- purely cosmetic treatment of a human by administration of a chemical product (see T 144/83).

### Yes – a method of treatment

- A cosmetic treatment involving surgery or therapy



## EXAMPLE

A use of cosmetic and dermatologic preparations comprising one or more compounds selected from the group comprising ....

b) a combination of compounds selected from the group comprising ...

for lip protection and the prophylactic treatment of stinging and unspecific itching, for stabilizing the epidermal barrier.

→ violates Art. 53 c) EPC, because therapeutic treatment is within scope of protection



## Avoid the therapy / surgery trap

Non-therapeutic use of cosmetic preparations comprising

- a) one or more compounds selected from the group comprising ....
- b) a combination of compounds selected from the group comprising ...

for lip protection and the prophylactic treatment of stinging and unspecific itching, for stabilizing the epidermal barrier.

- Disclaimer of therapeutic use not admissible
- Claim is unclear, Art. 84 EPC, therapeutic use disclaimed, but still within scope of protection “prophylactic treatment”



## Avoid the therapy / surgery trap

Non-therapeutic use of cosmetic preparations comprising

- a) one or more compounds selected from the group comprising ....
  - b) a combination of compounds selected from the group comprising ...
- for lip protection and protection of the skin from stinging.

- Claim is clear, Art. 84 EPC
- No therapeutic within scope of protection
- Wording is critical: “prophylactic treatment” belongs to therapeutic treatments, restoring skin after damage belongs to therapeutic treatments





## Avoid the therapy / surgery trap

### Board of Appeal Decision T 67/02

The Board sees in the first auxiliary request a clear differentiation of the claimed use [from therapy], since it does not apply to the treatment of already formed itching, but a protection is provided against external toxicants. **It is therefore clearly a "non-therapeutic" use to shield the skin**, which can be considered acting as a quasi cosmetic glove.



## Avoid the therapy / surgery trap

### Board of Appeal Decision T 383/03

If a method involving a physical intervention on the human or animal body (treatment by surgery) is clearly neither suitable nor potentially **suitable for maintaining or restoring the health, the physical integrity, or the physical well-being of the person or animal**, then the method does not fall under the exclusion from patentability provided for in Article 52(4) EPC



## Avoid the therapy / surgery trap Practical Advice

- At least one feature or step defining a physical activity or action that constitutes a method step for treatment of a human or animal body by surgery or therapy is sufficient for falling under the exclusion of Art. 53 c) EPC
- The non-patentable subject-matter must be removed – this can be achieved either by a disclaimer or by omitting the surgical step from the wording of the claim
- But: Surgical instruments are patentable subject-matter



## Subject-matter of patent protection

- Composition of matter:
  - new compound
- First medical indication:
  - Compound known, but not for use as a medicament
- Second medical indication:
  - Compound known, use as a medicament known, but not use as medicament for the treatment of *new indication*
- US: Method of treating, inhibiting, predicting, Monitoring, limiting disease, effects of disease



## IP Strategy

- Analysis of prior IP rights to
  - avoid dependent rights
  - obtain protection (dancing around raindrops)
- Disclose enough without being too specific
  - „chemical rooms“
  - Possibility to define “R” in a Markush-claim and relate it to specific advantages



## EXAMPLE

- ICI held a patent in which fluconazole was covered by a Markush-claim, but was not specifically exemplified
- Pfizer made fluconazole and found that it had some distinct advantages versus the closest examples disclosed in the ICI patent:
  - lack of teratogenicity
  - better solubility
  - better antifungal potency
- Pfizer obtained a patent of selection





## IP Strategy

- Avoid to provide a template for others (Big Pharma)
- Withdraw your application prior to publication if the lab is behind schedule
- Use priority year for obtaining a search report (UK, LU)
- Pay attention to national regulations (China: it is not possible to provide further experimental data during prosecution)
- Prepare the right data for supporting the claims  
(treatment of disease)
- Be careful when disclosing your assays as the might enable others to follow you



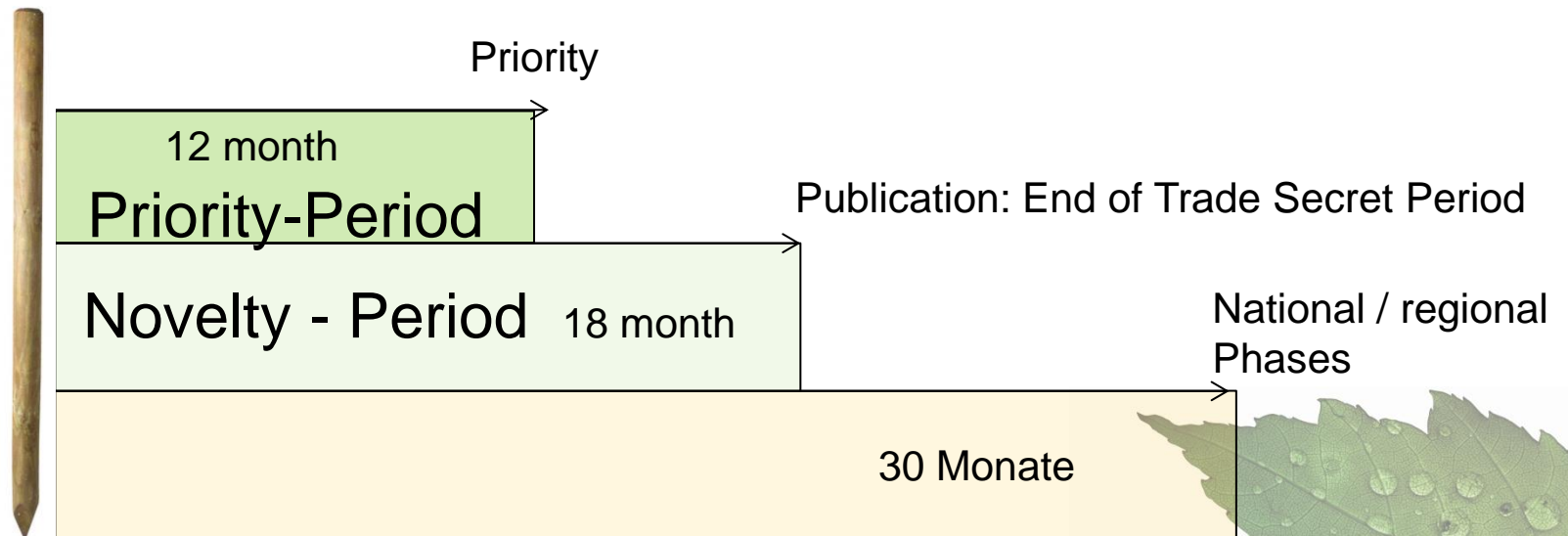
## Baiscs of IP Protection

- File before publishing
  - Press release, Request Clinical Trials
  - Abstract books
  - Online publishing ahead of printing
  - Negotiations without NDA
- Is the invention complete or in progress?
- What about competitors?
- Alternative Solutions?
- Circumventions?
- Are we still protecting the product?



## Schedule of IP protection

First filing



## Priority

- First filing fixes a date for relevant prior art
- Priority is a 12 month period from your first filing
- Without publication, each filing is suitable to let a new priority commence → withdraw first filing
- Use search results in subsequent filings
- Don't worry to put more than one invention (different chemical structures) in one first filing to create a priority date for all inventions



## Priority and further prosecution

- Use one first filing as priority for multiple subsequent filings (composition of matter, method of manufacture, use as a medicament, treatment of disease 1, treatment of disease 2)  
→ create multiple rights for multiple licenses



## Publication

- End of trade secret period → others see what your are working on
- Up to publication the subject matter of subsequent filings for further developments only has to be new as regards the first filing → unpublished first filings will not be considered for examining inventive step
- File for a new chemical formulation based on new experimental results
- Combine prior national applications



## National / Regional Phases

- Think careful about the right countries/regions
  - manufacture and distribution
  - potential licensees
- US offers the opportunity of Continuation-In-Part (CIP) → you may add new matter and benefit from priority
- China: You are not allowed to provide further experimental data during prosecution





## National / Regional Phases

- Russia /Japan: Claims have to be literally comprised within description
- Singapore: Chose the right route for your application



## Direct patent prosecution in the right direction

It's all in **Article 84 EPC**

“The claims shall define the matter for which protection is sought.

They shall be

- **Clear** and
- **Concise** and
- **be supported by the description.**



## Direct patent prosecution in the right direction

- Claims define the subject of
  - Search
  - Examination
  - Protection
- Applicant defines subject matter of prosecution
- Take care of remaining in the field of cosmetics



## Patent Description Rule 42 EPC

- (a) specify the technical field to which the invention relates;
- (b) indicate the background art which, as far as is known to the applicant, can be regarded as useful to understand the invention, ....;
- (c) disclose the invention, as claimed, in such terms that the technical problem, even if not expressly stated as such, and its solution can be understood, and state any advantageous effects of the invention with reference to the background art;
- (d) briefly describe the figures in the drawings, if any;
- (e) describe in detail **at least one way of carrying out the invention** claimed, using examples where appropriate and referring to the drawings, if any



## Intermediate Generalization (Intermediate Limitation)



- Intermediate generalization refers to the deletion or addition of single features from a combination
- feature is not related or inextricably linked to other features of an embodiment?
- does the overall disclosure justify the generalizing isolation of the feature and its introduction into the claim



## Case study: Intermediate Generalization



- Application refers to a prosthesis with two interacting elements
- figures show annular surfaces for both elements
- description refers for one element to an edge and for the other partner to an annular surface



## Case study: Intermediate Generalization



### EPO:

- Allowable with wording of description
- Skilled person will not take from figures annular surfaces for both elements, but interacting edge and annular surface

### USPTO:

- amended claim with both elements having annular surfaces does not introduce new matter, disclosed in figures





## Intermediate Generalization Practical Advice



- Describe all conceivable combinations of features and relate technical effects
- Explain advantages of the technical effects
- Provide examples distributed through claimed ranges, not only to an upper or lower limit
- Provide examples for alternatives and not only for a single representative of a group of compounds

## Intermediate Generalization Practical Advice



- Provide definitions grouping compounds by common properties
- Relate conditions for application to as many combinations (and indications) as possible
- It is very difficult in Europe to take features from figures into claims
- When filing PCT, get in contact with a European Patent Attorney

## Unity of Invention – Art 82 EPC

“The European patent application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept.”

- Might be contested in search report of first filing → no search for further inventions
- Assessment of offices may vary
- Be sure that the USPTO will issue a restriction requirement (35 U.S.C. § 121)



## Patent Application

- Probability of Grant
  - Prior Art
  - Comments in Search Report
  - Number of Office Actions
- Protectable Subject Matter
  - Any Restriction Requirements issued?
  - Continuation/Divisional Applications



## Patent Application

- Time factor
  - Divide to speed up grant of allowable matter
  - Think about procedural steps to speed up grant (appeal in favor of further Office Actions)



## Grant of a Patent

- Do you still protect your final product  
→ relate product development and patent prosecution
- Did the Examiner work properly?
- Or did he/she want to get rid of your application by allowing it?
- Do you think your patent is enforceable?





## Integrated IP Portfolio

- Patent protection is not the be-all and end-all
- Build a wall around your technologies using all kind of IP rights
- File for trademarks to name your technology
- File for designs for disposables
- File applications for further developments to extend time of protection → let the Examiner decide whether a further development is new and inventive





## Quality of your patent

- Do not produce a graveyard of features
- Take care of clear and understandable claims → the judges are no technical experts
- Are you really the owner of your rights or are there national regulations giving employees rights on inventions?
- Do not hold back information
- Disclose all prior art you are aware of (or others will do)
- Take care about national regulations  
→ duty to use patents (Turkey, India)

## Quality of your Patent

- Avoid dependent patents: medical use dependent on compound of matter
- Limitations due to contracts with third parties
  - collaboration agreement allows only non-exclusive licenses,
  - collaboration partner has a non-exclusive license,
  - both partners are allowed to exploit inventions independently
  - Ownership unclear → law on employees' inventions



## Development of a Patent Portfolio

- All-in only for filing: save time and money
- Use can be the most valuable part of a patent
  - Do you remember Viagra?
- Gore-Tex:
  - Patents on basic PTFE process
  - One basic patent on fabric laminates
  - 100s of patent on use
- Supplementary Protection Certificate
  - Once for a patent and not for every compound in one patent → split up an application for different compounds / use



## Trademark, Company Name, Designs

### Flanking technical IP rights

- Trademark
  - Name, identity of a product
    - Goods and Services
  - Enables to name a specific product/use
- Company Name
  - Separates your company from others
- Design
  - Protects the appearance of a product (MedTech)



## Trademark, Company Name, Designs

- Ownership
- Regional extension
- Similar trademarks of competitors dilute protection/portfolio
- Co-Existence Agreements
- Use in manner to preserve your rights
- Good way to monitor competitors





## Do you have an IP Strategy?

- Flanking protection of core technology?
- Extension of time by filing applications for further developments?
- Protection in the right territories?
- Cost control?
- One strategy for all patent families?
- Monitoring competitors
- Are IP and product development in accordance?



## IP relevant Agreements

- R&D contracts
- Collaboration agreements
- Work programs (Horizon 2020)
- Tech Transfer or MTA
- License Agreements



## IP relevant Agreements

- Agreements transferable (by acceptance)
  - + Secure Freedom-To-Operate (FTO)
  - Access to background IP has to be granted
- License Agreements
  - Clear definitions on what will be licensed
  - Non-exclusive, exclusive
  - Compliance with legal provisions
  - Period
  - Define termination rights
  - Who is responsible for: renewal, infringements ...



## Your Patent is dependent?

- Purchase
- Cross-License
- Circumvention
- Form a Patent Pool

→ Do not ignore others rights !



## How to deal with others IP rights

- Assess probability of infringement proceedings
- Assess success rate (carefully!)
- Evaluate validity of others rights
  - Supplemental search
  - Analyze patent portfolio, sometimes prior art can be found in the portfolio of the patent proprietor
- Use your own IP to create willingness to negotiate



## Prepare for Negotiations

- Does your technology possess unique features
- Easy to copy- low entry barrier for competitors
- Group of Owner
- IP rights are challenged
- FTO given



## Summary

- Claims define the scope of protection
- Disclosure is relevant, but avoid
  - Holding back necessary information for a strong patent
  - Providing a blueprint for competitors
- Flanking IP rights protect your core technology
- Proactively work on your IP portfolio
- Monitor whether patent prosecution and product development walk hand in hand
  - Withdraw applications prior to publication
  - File new applications – prior to publication





## Summary

- Proper Documentation
  - Sale/ Licensing of overhang
  - Purchase/ Licensing of IP rights for FTO
- Don't forget: IP serves business needs – don't collect certificates
- Don't just rely on inventors to submit ideas
- Talk to investors, no need to file patents without invention
- Let IP serve your business needs
- Monitor your competitors



## Questions?

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