European
IP Helpdesk

www.iprhelpdesk.eu

European IP Helpdesk

Stay ahead of the innovation game.

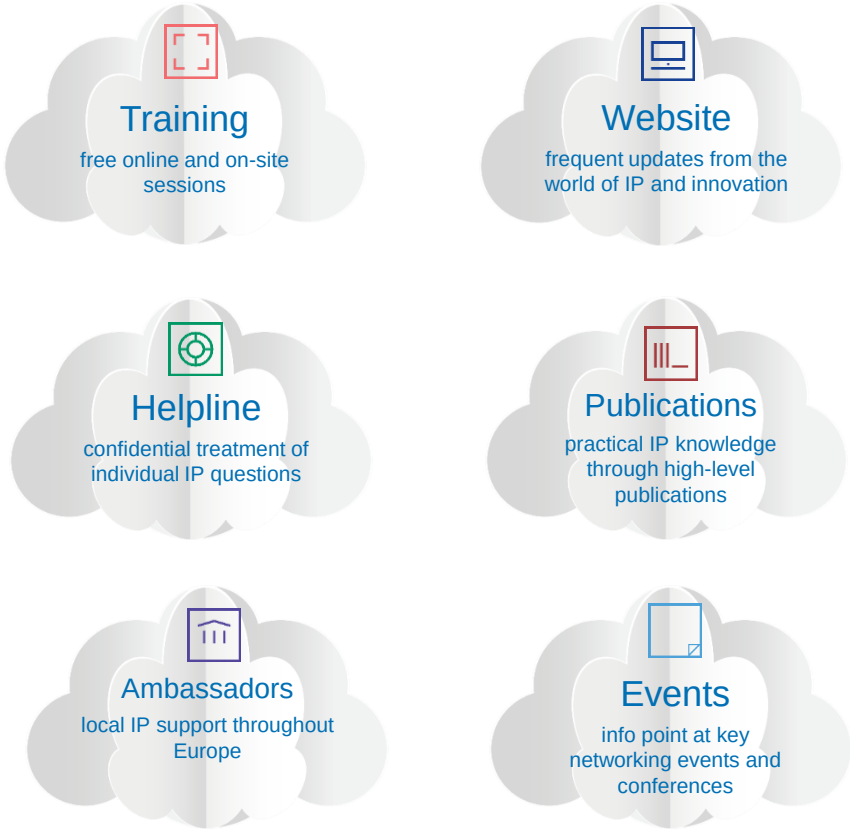
IP in Biotechnology

03.02.2021

European IP Helpdesk

- Service initiative of the European Commission
- Addressing **current and potential beneficiaries of EU-funded projects, researchers and EU SMEs**
- Free-of-charge first-line support on intellectual property (IP)
- Hands-on IP and innovation management support
- International pool of IP experts from various thematic fields
- Unique cooperation scheme with the Enterprise Europe Network: 47 ambassadors from 28 EU countries

NEW URL:
ec.europa.eu/ip-helpdesk



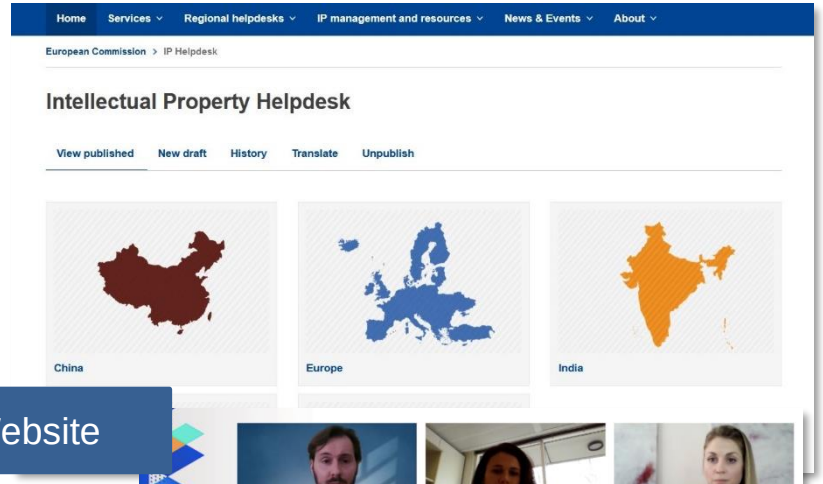
The EC IP Helpdesks

INDIA
IP SME HELPDESK

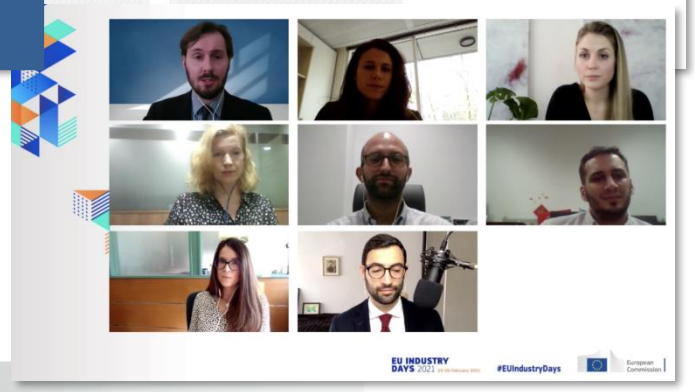
European Commission

ec.europa.eu/ip-helpdesk

Communication Formats & Outreach Tools

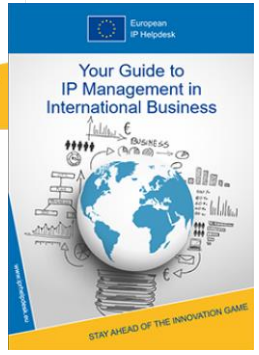


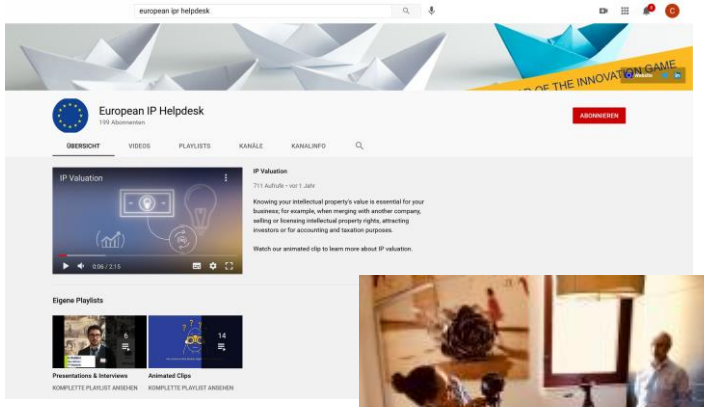
Website



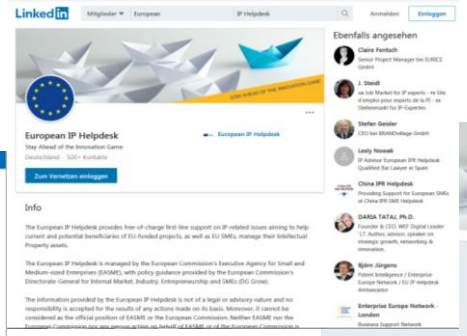
Training

Publications





Audio-visual Content



Social Media

Helpline

- Free-of-charge, first-line IP support
- Personal and “to the point”
- Answer within 3 working days
- Email, phone and web
- In: English, Spanish, French, German, Italian and Polish
- Confidential

Europe - Upcoming events

28 APR 2021
TRAINING AND WORKSHOPS
EU - Webinar: Freedom to Operate
Live streaming available

05 MAY 2021
TRAINING AND WORKSHOPS
EU - Webinar: IP and Artificial Intelligence
Live streaming available

12 MAY 2021
TRAINING AND WORKSHOPS
EU - Webinar: IP in Biotechnology
Live streaming available

19 MAY 2021
TRAINING AND WORKSHOPS
EU - Webinar: IP Management in ICT Projects
Live streaming available

20 MAY 2021
TRAINING AND WORKSHOPS
EU - Webinar: IP in EU-funded Projects
Live streaming available

26 MAY 2021
TRAINING AND WORKSHOPS
EU - Webinar & CPVO coop: IP rights in Agri-food Sector: a Guide to Geographical Indications, Trademarks, Patents & Plant Variety Denominations
Live streaming available

09 JUN 2021
TRAINING AND WORKSHOPS
EU - Webinar:The new Copyright Directive
Live streaming available

16 JUN 2021
TRAINING AND WORKSHOPS
EU - Webinar:IP Commercialisation & Licensing - Advanced
Live streaming available

23 JUN 2021
TRAINING AND WORKSHOPS
EU - Webinar: Effective IP and outreach strategies to help increase the impact of research and innovation
Live streaming available

07 JUL 2021
TRAINING AND WORKSHOPS
EU - Webinar: Maximizing the Impact of Horizon 2020 project results
Live streaming available

Recording

Please note that the whole presentation, including the Q&A session, is recorded. The presentation will be sent to you after the webinar.

Contact:

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Stay ahead of the innovation game.

Dr. Sebastian Tegethoff, Patentanwalt /
European Patent and Trademark Attorney

Suspension on patent rights on vaccines?

- Is thought to help developing countries to secure vaccines against coronavirus
- But: Is a substantial intervention into intellectual property rights
- Patent rights can be regarded as a reward for securing technical inventions
- It is not a question of intellectual property but a political decision which has to be made
- Discussions are held at WTO
- Not surprising: Countries where companies are located holding important patents are reluctant

Intellectual Property

Creations of the mind, such as:

- technical inventions
- literary and artistic works
- designs
- symbols
- names and images

used in commerce.

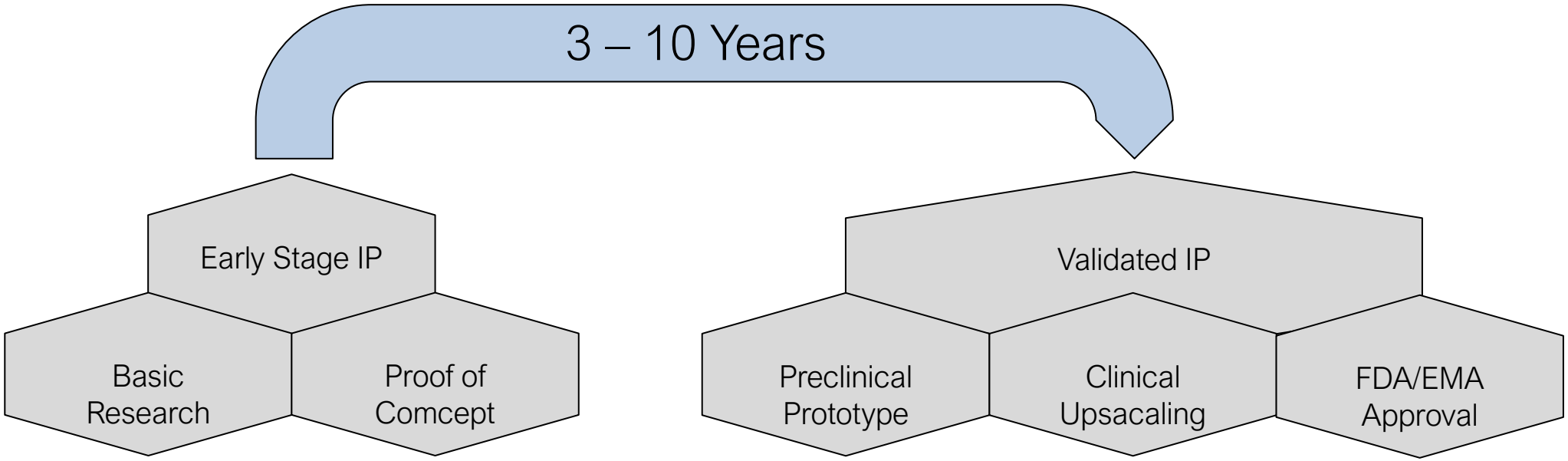
Intellectual Property

- Compulsory for successful exploitation
  - Manufacturing
  - Founding
  - Licensing
- IP-strategy necessary for efficient cost control
  - First filing
  - Territories
  - Smart IP: patent / trademarks / designs
- Connect your IP to product development

Intellectual Property Strategy

Is a dynamic process accompanying the inventive process.

IP and Product Development



Manage IP actively

Apply early (enough) …

… but adjust your IP to further development (within years).

Manage IP actively

- No publication prior to filing patent applications
- distinguish technically different inventions (unity of invention)
- Monitor further developments
- Adjust pending applications
- Keep clear about ongoing publications (scientific and patent applications)

The secret of patenting

Article 84 EPC (European Patent Convention)

"The claims shall define the matter for which protection is sought. They shall be
-**Clear** and **Concise** and
-**be supported by the description**

The secret of patenting

Claim contains ⊆ technical feature(s)

Distinguishing from prior art to obtain ⊆ technical effect

Grant ⊆ resulting advantage

When to file

Can you describe a technical problem and its technical solution?

- It’s not about results to be achieved.
- Characterize your invention with technical features (or parameters)

Example:
What technical property defines the binding specificity of an antibody?
Sequence, required amino acids, modified amino acids……

What to protect?

→ Compound / Composition of matter

→ Process for the production of a compound / composition

→ Use of a compound/composition of matter for treating a disease
- First medical use: first use as a medicament
- Second medical use: first use as a medicament for a specific indication

→ Treatment/Prevention of a disease
(Take care, not allowed in Europe but in the U.S.)

Direct patent prosecution in your direction

→Tell the whole story, do not keep any important features

→Enablement is important: clear, concise (Art. 84 EPC; 35 USC 112a)

→ describe all embodiments and combinations of features

→ EPO is very strict about ”intermediate generalizations”
- Addition or deletion of features has to be disclosed in its context
- Don’t rely on implicit disclosure

→ connect advantages to embodiments / feature combinations

Direct patent prosecution in your direction

→do not keep any relevant prior art
- Disclose it
- Distinguish your invention from it
- Discuss it in the detailed description, anticipate examination report(s)

→Think carefully about the scope of your disclosure, it may conflict with subsequent applications

→Stick to the facts, be careful when speculating which may anticipate further inventions

→First to file, than to disclose it in public

Direct patent prosecution in your direction

→ Provide enough examples, otherwise you may
- be restricted to compounds mentioned in the examples
- not get the protection you really need, use as a medicament

→ Provide the correct examples as regards the claimed medical use of a product

→ Take care that a claimed use does not serve to maintain or restore health, physical integrity or well-being of a human or animal (in Europe)

Avoid the therapy / surgery / diagnostics trap

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

Defining the Boundary Line of Admissibility

→At least one feature or step defining a physical activity or action that constitutes a method step for the 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: Devices like surgical instruments are patentable subject-matter

Defining the Boundary Line of Admissibility

→Fixing a measuring device that is indispensable for the method's performance may define a surgical step (T 932/08)

→Treatment by surgery is not limited to therapeutic methods, may also affect cosmetic applications

Filing strategy

→ An invention is made, when when there is a conception and reduction to practice

→ Use a first filing for obtaining a search report, this is the cheapest way to get an official opinion

→ No experimental results needed for first filing,
but for “final” filing for getting a patent granted

Examples for filing strategies

Classic

- First Filing: national filing
- Language: national language (German, English, French, Italian…)
- Fees: 300 - 500 Euros
- Disadvantage: Language, Territory

Luxury

- First Filing: European Patent Office (EPO)
- Languages: German / English / French
- Fees EPA: around 1.500 Euros
- Disadvantage: Costs

Exotic

- Provisional: United States Patent and Trademark Office
- Language: Englisch
- Fees USPTO: 280 USD (Application Large Entity)
- Disadvantage: No search report

Filing strategies

1) Aim is publication only
   → Generate prior art

2) Aim is grant of a patent
   → Obtain enforceable IP right

1) Aim: Publication

- Application in UK
- Official Fees: 150 £
- Language : English

(Subsequent filing possible if search report is positive)

2) Aim: Grant

- Quality of Search Report
  - cited prior art: relevant?
  - Enabling amendment of claims
  - Speed up grant
  - Reduce costs

- Having your place of business within EU requires filing PCT applications via EPO

2) Aim: Grant

In essence:

- Low cost
- High quality

Solution: National-to-European Application

National-to-European Application

- Several countries in Europe (France, Luxembourg, Netherlands, Belgium, etc.) use the European Patent Office as the Search Authority for a national patent application.
- The applicant receives a European-style search report
- 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).
- It is possible to anticipate a major part of the European examination procedure.
- A European application will benefit from the prior search results
- The search fees of national authorities are usually lower than the European search fee

National-to-European Application

- In case that the EPO is the national search authority, experience shows that the same examiner who searched the national case will generally be in charge of examining the later European application.
- The patent search will not be repeated after filing a European application and at least some of the fees paid at the national stage will be credited against the costs of the European search.
- The advantage of this National-to-European strategy is that, even if relevant prior art is found, a broader degree of freedom is given for revision of the application in comparison to a European application being on file which has been searched.

Example Luxembourg

- An example for a National-to-European strategy using the EPO as search authority for the national and European filing is to file a national application in Luxembourg.
- The Luxembourg application can be filed in French, German or English.
- In the case of an English language application, only the claims need to be translated at a later stage. A translation of the whole description is not necessary.
- The cost of the European-style search report is for Luxembourg is very low at only 250 Euros.

Community Patent – a long, long story ...

- A real unitary European patent
- Should have been in place for at least 2 years
- Brexit and constitutional issues in Germany are making it impossible to predict, when this new kind of European patent will come into force

... still going on

Aspects for the development of an IP strategy

Aspects for the development of an IP strategy

- Definition of dependencies between subject-matter
- Is an application for one subject-matter suitable for anticipating another subject-matter?

- → If yes, all applications need to have the same first filing date!

Aspects for the development of an IP strategy

- First filing should be placed if subject-matter can be described using technical features for characterization.
- With respect to costs a first filing should be placed via Luxembourg
  - To get a first search report on patentability
  - To get insight in relevant prior art
  - To get insight whether freedom-to-operate is given

Aspects for the development of an IP strategy

- Careful analysis of search report
- Probably withdrawal of first filing for placing a “new” first filing
- Proceed only when sufficient data is at hand

Aspects for the development of an IP strategy

- If necessary create a chain of first filings until basic subject matter is clear

LU2 may use information from search report LU1

Subject matter of LU2 and LU3 may be adjusted to results search report and ongoing development

Alternatives to patent applications

Alternatives to filing patent applications

- Patent applications will be published 18 months from the first filing date
- Competitors will get hindsight what you are working on
- Filing patent applications omitting essential features is contrary to a good IP strategy
- A decision has to be made whether to file an application or to handle an invention as trade secret

Handling of trade secrets

- Whoever gets knowledge of a trade secret has to be aware of the trade secret
- The subject-matter or the basic technical fields of a trade secret has to be defined
- The EU has a directive concerning the protection of undisclosed know-how and business information (Directive EU 2016/943)

Directive EU 2016/943

(1) "trade secret" means information which meets all of the following criteria

(a) it is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) it has commercial value because it is secret;

(c) it has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret;

- → A trade secret relates to information that is not publicly known and can be controlled

Directive EU 2016/943

- Definition of a trade secret holder

(2) 'trade secret holder' means any natural or legal person lawfully controlling a trade secret;

→ Not belonging to the public

- Consortium members
- CROs
- Collaborating companies/academia
- Patent offices
- Attorneys

Handling of trade secrets

- Agreements are necessary to clarify the handling of trade secrets
  - Non-Disclosure Agreements (NDA)
  - Collaboration Agreements
- Regulations concerning known secrets and future knowledge based on secrets will have to be negotiated
- Remember: It will not be possible to seek for patent protection when the invention is based on the use of a trade secret

Handling of trade secrets

- Define
  - The information that has to be kept secret
  - The circle of people having access to the trade secret
  - Who is the owner of the secret information, which
    - Is known so far and
    - which may arise from the known secret information
  - Who is allowed to work/exploit the information forming the trade secret

Handling of trade secrets

- Create data rooms with different levels of access
- Use of data room is compulsory
- No copies on mobile or stationary devices are allowed without NDA
- A pending patent application has prior to its publication to be regarded as a trade secret

Back to patenting

- At a certain time, the decision may be made to seek for patent protection
- End of trade secret after 18 months from first filing of a patent application due to its publication
- The 18 month are often designated as ‘trade secret period’
- Withdrawal of a pending application prior to its publication extends the trade secret period (but requires a new filing if patent protection shall be obtained)

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