European IP Helpdesk

Stay ahead of the innovation game.

Ip in Biotechnology

09 02 2025

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: 43 ambassadors from 26 EU countries

Training
free online and on-site sessions

Website
frequent updates from the world of IP and innovation

Helpline
confidential treatment of individual IP questions

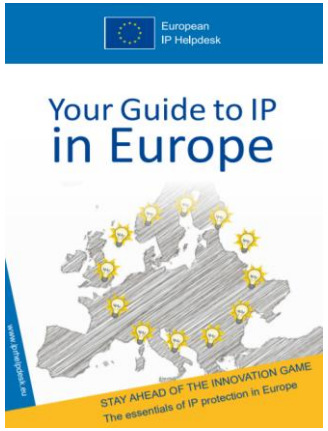
Publications
practical IP knowledge through high-level publications

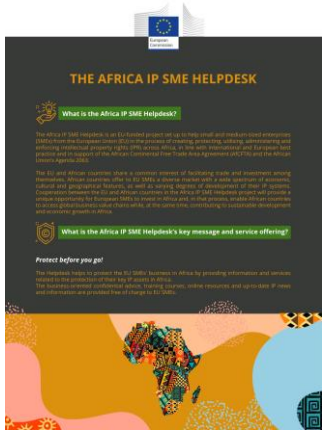
Ambassadors
local IP support throughout Europe

Events
info point at key networking events and conferences

The EC IP Helpdesks

EC IP (SME) Helpdesk Hub – Gateway to Information





- E-learning modules & more
- Guides / Topic, country, sector-specific factsheets / Infographics
- Case studies

Ambassador Scheme

- **Cooperation scheme** with the Enterprise Europe Network (EEN): 43 ambassadors – 26 countries
- **Building IP capacities** among European SMEs
- **Overcoming language barriers**
- Making the topic **more accessible**
- Exchange and feedback from ambassadors on **needs of SMEs**
- Local **awareness** and **training events**

Upcoming events

06 FEB 2026
Training and workshops
EU - Webinar: Introduction to IP
Live streaming available

09 FEB 2026
Training and workshops
EU - Webinar: IP in Biotechnology
Live streaming available

12 FEB 2026
Training and workshops
EU-13 Roadshow: From Innovation to Impact – Knowledge Valorisation and Commercialisation Strategies
Gdańsk, Poland

12 FEB 2026
Training and workshops
EU - Webinar: IP Management in ICT Projects
Live streaming available

18 FEB 2026
Training and workshops
EU - Webinar: Technology Transfer
Live streaming available

24 FEB 2026
Training and workshops
EU - Webinar: Consortium Agreements
Live streaming available

25 FEB 2026
Training and workshops
EU - Webinar: IP in Horizon Projects (HEU)
Live streaming available

26 FEB 2026
Training and workshops
EU - Webinar: Copyright in collaborative projects
Live streaming available

03 MAR 2026
Training and workshops
EU - Webinar: IP in EU funded projects with a special focus on MSCA
Live streaming available

05 MAR 2026
Training and workshops
EU - Webinar: IP Assessment
Live streaming available

12 MAR 2026
Training and workshops
EU - Webinar: IPR and Software
Live streaming available

17 MAR 2026
Training and workshops
EU - Webinar: IP Commercialisation and Licensing
Live streaming available

Thank you!

- www.ec.europa.eu/ip-helpdesk

- helpline@iprhelpdesk.eu
- training@iprhelpdesk.eu

- Twitter @iprhelpdesk

- LinkedIn /european-ipr-helpdesk

Intellectual Property (IP)

Creations of the mind, such as:

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

used in commerce.

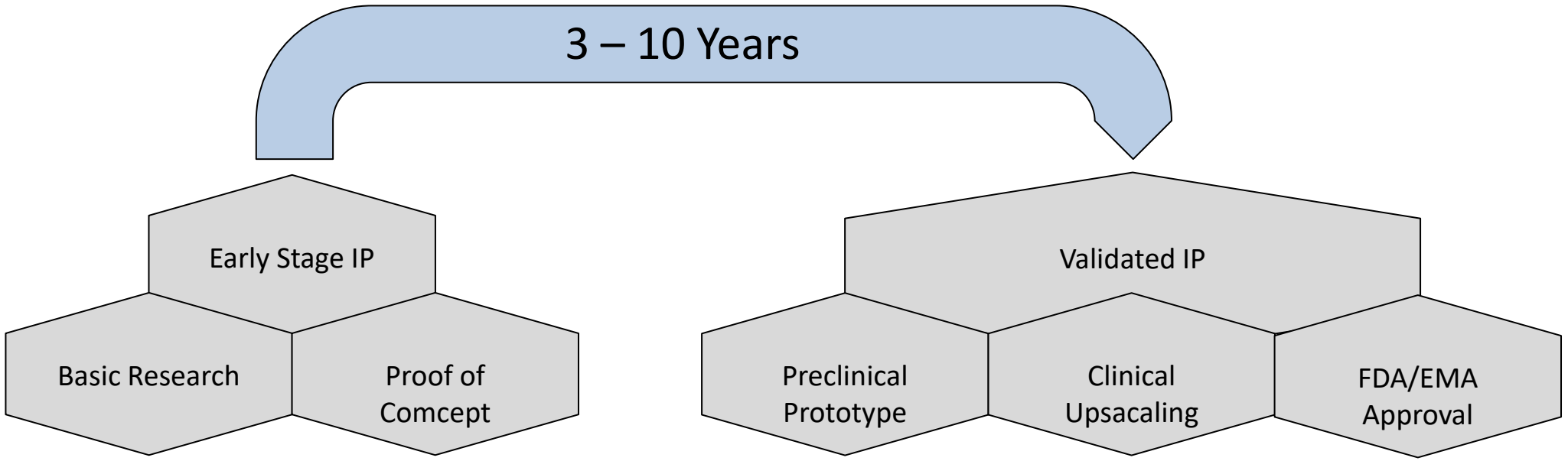
Intellectual Property, is …

- … compulsory for successful exploitation of inventions
  - Manufacturing
  - Founding
  - Licensing
- … part of an IP strategy which is necessary for efficient cost control
  - First filing
  - Territories
  - Smart IP: patent / trademarks / designs
- … to be connected to the product development

IP Strategy

Is a dynamic process accompanying product development.

Synchronize IP and Product Development



Manage IP actively

Apply early (enough) …

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

Discovery vs. Invention

Discovery …

… is the observation of new phenomena, new actions, or new events which have been present.

Invention…

… is a novel, inventive, and industrially applicable solution to a technical problem, often a new product, process, or method.

Discovery vs. Invention

Discovery

Not patentable.

Example: Naturally occurring genes, proteins, microorganisms. Discovering naturally occurring biological processes.

Invention

Patentable.

Commonly the application of discoveries, like blocking or enhancing naturally occurring processes.

Discovery vs. Invention

Distinguishing criteria:

1.Has the material been **technically removed from its natural environment**?
2.Is a **specific technical use** specified?
3.Is this use **reproducible**?

➞ No patentability without specification of function (e.g., “Gen X without known function”).

What can be protected

- DNA/RNA sequences with function
- Vestor, plasmids
- Proteins, antibodies (including humanized ones) with function
- Cell lines, hybridomas
- Genetically modified organisms
- Biotechnological manufacturing processes

What can be protected

Special feature of biotechnology:

- The substance itself is the subject of protection, not just a device or process
- Protection extends to **any reproduction** (self-replication!)

➞ Classic technology: Use → Biotechnology: **Reproduction = infringement**

What can be protected

- Genetic engeneering techniques
- Microorganisms
- Genetic features which show an effect across varieties

➞ sufficient disclosure is crucial

Enablement

The skilled person must be able to reproduce the invention **without undue burden**.

Particularly critical in the case of:

- functional antibody claims
- screening methods
- gene definitions without sequence information

→ Years of trial and error are **unreasonable**.

Enablement

Biological systems have to be described completely.

- **Deposit requirement** (Budapest Treaty)
- Deposit, e.g., with DSMZ
- Must be **accessible** to experts
- Filing of a sequence protocol required

➞ Without proper deposit: **invalidity** of the patent possible.

Ethical Exclusions

- Human cloning
- Germline modifications
- Industrial use of embryos

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

Claim Drafting

- “Gene Sequence X / Amino acid sequence Y for us as/in….”
- “Compound X, comprising …” (Compound = novel, unknown chemical structure)
- “Compound X for use as a medicament.” -> First medical indication
- “Compound X for us as a medicament for the treatment of….” -> Second medical indication

Claim Drafting

- Define functional features of a sequence: …for the treatment of…comprising activity Y….
- Define sequence homologies

Scope of Protection

- Reach-through-claims are not allowed

BUT

- Protecting a sequence will encompass all later possible uses

Scope of Protection

Permitted is the search on the invention or a verification.

Forbidden is the use of an invention in commerce.

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 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 or pharmaceuticals used in therapy are patentable subject-matter

Defining the Boundary Line of Admissibility

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

→Treatment by surgery is not limited to therapeutic methods: the exclusion from patentability may also apply to cosmetics

When to file

An invention is “ready” when you can describe a technical problem and its technical solution.

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

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

When to file

→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 on relevant prior art

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

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 with respect to the claimed medical use of a product

Example: Good expression of a protein does not give evidence on effects of reducing tumor growth.

→ 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)

Examples for filing strategies

Classic

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

Classic luxury

- First Filing: European Patent Office (EPO)
- Languages: German / English / French
- Fees EPA: around 1.800 Euros
- Disadvantage: Costs
- Advantage: Language, Territory

Exotic (recommended when US inventors contributed)

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

Why do you file an application?

1) Aim is publication only
   → Generate prior art

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

1) Intention of Filing: Publication

- Application in UK
- Official Fees: around 170 £ (including search fee)
- Language: English

(Subsequent filing possible if search report is positive)

2) Intention of Filing: 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) Intention of Filing: 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 at only 490 Euros, which is about 1/3 of the European fees.

Aspects for the development of an IP strategy

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
- Do your homework by considering Examiner’s objections
- Probably withdrawal of first filing for placing a “new” first filing
- Proceed only when sufficient data is at hand

Alternative to a patent application

Alternatives to a patent application

- Patent applications will be published 18 months calculated 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 must be aware of the trade secret
- The subject-matter or the basic technical fields of a trade secret must 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

- 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)

Questions?