Scaling up the commercialization of R&D

Curriculum Course

Output: Activity 2.2

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Spis treści

Part 1: Intellectual Property

1.1 What is intellectual property (IP)

Intellectual property, in its colloquial sense, refers to creations of the human mind. However, for the purposes of this Curriculum, a more specific approach is necessary. In a strict sense, intellectual property is a concept that encompasses two notions, namely property and intangible goods. While property is intuitively associated with tangible objects, the law has extended it to include intangible goods in response to the need for protection of creators and inventors. Intellectual property, in the strict sense, refers only to objects that are created by the human mind and are recognized and protected by law. This means that IP, sensu stricto, does not refer to all intellectual outputs, but only to those that are legally defined. Intellectual property covers a vast range of creations of human intellect for example works of art, inventions, designs, computer programs, trademarks, images.

What does it mean intangible goods?

The term of intangibility can be illustrated by an example of a work protected by copyright. Imagine that a poet creates a poem and makes only one copy of the poem, for example on a notebook, or in digital form on his tablet (in legal terms the poem is "fixed"). The poem is entitled "*Blue*". Copyright protection of the "*Blue*" poem exists regardless of the tangible carrier on which the poem is recorded. We may ruffle the notebook in which the poem is written or destroy the tablet in which the poem is recorded, however, it would still be protected by the copyright. In this example the only things destroyed are the material goods, namely the notebook or the tablet. However, the work still exists despite destroying the only physical carrier on which the poem is saved. The poem is protected by copyright despite destroying the only one copy of the poem that has existed.

The example above shows two types of property - the physical objects, namely notebook or tablet, are material goods and are subject to property rights. Those objects embody an intangible good – the poem "*Blue*" that is a subject to intellectual property rights.

Note:

Intangible goods exist separately from the material carrier on which they are fixed.

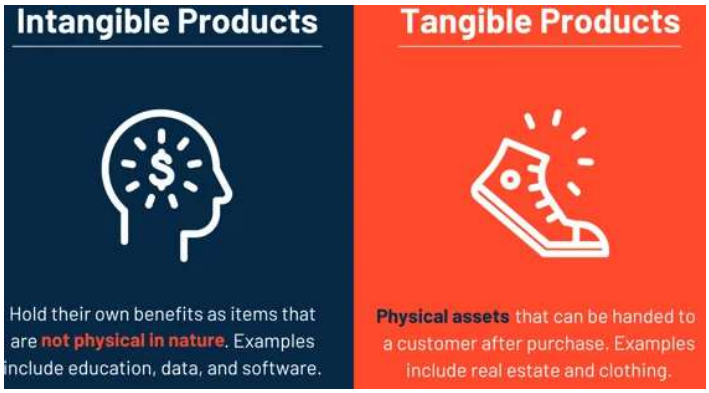


Fig.1: Intangible vs tangible goods. (https://www.g2.com/glossary/intangible-products-definition)

Intellectual property is non-rivalrous

"Non- rivalrous", or the opposite "rivalrous", are economical notions used to describe certain types of goods. If a good is rivalrous it means that it can be consumed simultaneously by one or limited quantity of consumers. Consuming such good by one consumer excludes others from using it at the same time.

On the other hand, non-rivalrous goods may be consumed simultaneously by an unlimited number of consumers (in the extremum). In other words, consuming a non-rivalrous good by one consumer does not prevent its simultaneous consumption by others. Most tangible goods are rivalrous.

For example, a jacket is a rivalrous good. If I put on a jacket other people cannot wear it at the same time. A bike or a car are other examples of rivalrous goods. Intellectual goods are non-rivalrous. In general, unlimited number of consumers may benefit from intellectual property simultaneously. An article may be read by an unlimited number of readers, and it will not be depleted. An invention may be implemented countless times without deprivation of its effectiveness. How many people listen to, or sing "*Imagine*" by John Lennon at the same time?

Is "Intellectual" always a creation of the human mind?

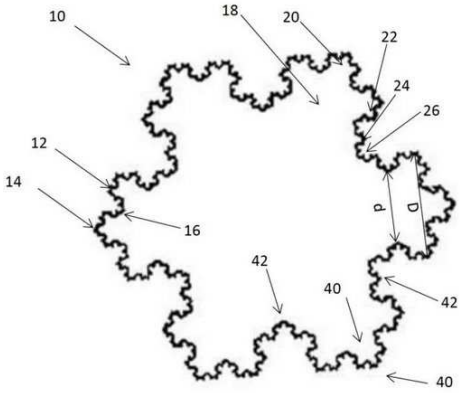
The adjective intellectual refers to the intellectual activity of a human. Most intellectual property laws are aimed at protection of human creativity or inventiveness. Therefore, the prerequisite of protection is that only the fruits of human creativity are protectable under those rights. However, not all intellectual property rights share the same goal. For example, a

trademark or a trade secret have different purposes and it is not required that the subject matter be the result of a creative or inventive process.

In the era of AI-driven inventions, literature, and images, we should take a closer look at the aspects related to the use of AI in creative activities.

Source: Monkey selfie copyright dispute - Wikipedia

When a British nature photographer, David Slater, was making photos, a macaque took his camera and took a selfie. Although the photo is unique, it cannot be protected under copyright, because it was taken by a monkey. Copyright protects solely works created by natural persons.



DABUS - Device for Autonomous Bootstrapping of Unified Sentience

Source: The Artificial Inventor Project

The Artificial Inventor Project, led by Professor Ryan Abbott, is intended to promote a discussion on the protectability of AI-generated output. Within the framework of the project a series of legal cases was filed to test whether intellectual property rights may be granted to an AI-generated output in the absence of a contribution from a human inventor or author. The vast majority of offices and courts around the world denied copyright or patent protection. Until this day, patent protection for AI generated invention was granted solely in South Africa.

Source: Théâtre D'opéra Spatial - Wikipedia

"*Théâtre D'opéra Spatial*" created by Jason M. Allen using the AI image generator "Midjourney", won first place at the Colorado State Fair Fine Arts Competition in the category "digital arts/digitally-manipulated photography". The image was a result of around 600 text prompts. The case contributed to the discussion regarding the boundaries of copyright law. The question which arose was whether the prompts could constitute a creative contribution to the image and in consequence might be protected by copyright, or whether is it necessary to edit the image manually for copyright to arise. Until now the U.S. Copyright Office (USCO) has denied copyright protection.

There is currently a debate on how to legally protect such outputs, as each approach carries different economic implications. Let us consider some hypothetical solutions.

1. Leaving AI-generated content entirely outside the scope of protection could undermine human creativity by introducing free and powerful competition for human-authored works and inventions. This could in turn deprive authors and inventors of the financial incentives to create.
2. On the other hand, granting full intellectual property protection to AI-generated outputs could slow down innovation and raises a fundamental dilemma: who would be the rightful owner?
3. A third option is the introduction of a *sui generis* right specifically tailored to AI-generated outputs. Such a right would be distinct from traditional intellectual property rights protecting human creations and limited in both duration and scope. In 2022, Ukraine became the first country to introduce a sui generis right for the protection of AI-generated content.

None of the solutions presented is flawless. However, at present, neither patent nor copyright protection is granted to the outputs of artificial intelligence.

The existing legal framework and the protection of AI-generated outputs

As a general rule, intellectual property rights protect human creations. However, protection of AI-generated outputs is not entirely precluded.

There are intellectual property rights that do not require human creativity or inventiveness as a condition of protection. For example, a trademark, the *sui generis* right to a database, or a trade secret may, subject to the fulfilment of the relevant conditions, also cover elements generated by artificial intelligence.

In the case of rights that exclusively protect human creations, such as copyright, industrial design rights, or patents, the protection of AI-generated outputs depends on the degree of human involvement in the creative process and the possibility of distinguishing the human contribution from that of AI. Three broad categories of AI-related outputs may be identified:

1. First, outputs entirely generated by AI are not eligible for protection requiring human creativity or inventiveness. Such outputs are therefore not protectable by copyright, patent, as an industrial or utility design, or as a new plant variety.
2. Second, AI-assisted outputs, where a human uses AI merely as a tool, are eligible for legal protection. In this category, AI serves as an instrument for example to perform analyses, introduce corrections or edits, or automate repetitive tasks.
3. The third category encompasses outputs that are AI-based or created with its substantial involvement, where the human role remains significant. This is the most contentious category. A notable example is "*Rose Enigma*" - an image generated by AI on the basis of a graphic drwan by an artist. Where AI is involved to such a degree, the question arises as to what is actually protectable and where the boundaries of protection lie. In such cases, the availability and scope of protection must be assessed on a case-by-case basis.

"Rose Enigma", Kris Kashtanova, 2023, source: https://www.kris.art/portfolio-2/rose-enigma

“Property”

Property means that solely the person possessing or entitled to a good may use it or dispose of it, excluding others from doing so. Such exclusivity may arise from possession or legal entitlement. Due to the fact that intellectual goods are intangible, the exclusivity of use may be granted solely by the legal system. Therefore, intellectual property is most commonly understood as the result of intellectual activity eligible for legal protection.

Note:

Intellectual property rights are exclusive rights!

Exclusivity means that only the owner of intellectual property rights can decide who is allowed to use a certain creation and under what conditions. This entitlement can be compared to ownership of physical objects (proprietary rights). For example, a car owner is the sole decision-maker regarding who can drive their car and on what terms. Moreover, IPR are objective rights, meaning they protect the rights holder against anyone in society.

Examples:

1. The author of the poem “*Blue*” is entitled to decide if the poem is communicated to the public or not, if it is published in a book of poetry or on the internet, if the access to the poem is granted upon payment, or free of charge, or whether it gets published on a billboard. No one else can make those decisions without the poet’s authorisation, unless they hold the copyright themselves, for example the poet’s employer or a publisher who acquired the rights from the poet.

2. Another example is the proprietor of the patent. Solely the person (or entity) entitled to the patent rights may use the invention commercially on a given territory where the patent is valid. The proprietor of the patent may authorise another entity to use the invention for commercial purposes (for example by licensing the patent).

Exclusivity means that the entitled entity may use the protected subject matter and exclude other persons from using it.

Intellectual property rights are, moreover, absolute rights, meaning that they are effective against all members of society enabling the rightholder to exclude any person or entity from using the intellectual property without authorisation.

Note:

Trade secrets do not confer an exclusive and absolute right in the classical sense. For the purposes of this course, however, the notion of intellectual property shall encompass trade secrets as well.

Exceptions and limitations

As outlined above, intellectual property rights are exclusive and absolute rights. However, it does not mean that the rightholder exercises unlimited control over a given intellectual property. Exclusivity is not absolute, and in certain circumstances a rightholder cannot prevent others from using protected intellectual property. National or regional law provides for specific exceptions and limitations to intellectual property rights.

Each category of intellectual property rights is subject to its own exceptions. These may include use for non-commercial purposes such as scientific research, teaching, quotation, private use, or parody.

Example:

In the EU national law may permit exceptions or limitations to copyright, allowing individuals to make copies of a work for their own private use. This is known as the private copying exception. Almost all national legal frameworks grant the right to quote from works that have already been lawfully made available to the public. A quotation is generally permissible if it serves a purpose defined under national law, such as teaching, criticism, or parody. Furthermore, the quotation must be proportionate to the intended purpose, and the source and author must be duly acknowledged. Such exceptions may be permitted under national law provided they are consistent with the general principles of international treaties.

In the case of industrial property rights protecting inventions, trademarks, or industrial designs, certain limitations arise from the scope of protection conferred by law. For example, a patent grants an exclusive right to exploit an invention for commercial purposes. However, use of the invention for personal and non-commercial purposes is generally permitted and falls outside the scope of the patent monopoly. National laws typically provide for exceptions for research purposes and transit. A specific exception developed in the pharmaceutical sector is known as the "Bolar exemption" - the name derives from the landmark case of Roche v. Bolar. This exemption permits certain acts in relation to a patented invention where they are necessary to obtain a marketing authorisation for a medicinal product.

1.2 Ways to protect IP

Why do we need to protect intellectual property?

There are several philosophical theories underlying the intellectual property system, such as the natural rights theory, the utilitarian theory, and the personality theory. In practice, intellectual property protection finds justification in all of these theories, which are not mutually exclusive. For the purposes of this course, however, we will significantly simplify the subject and focus on the economic perspective.

Development requires time, skills, knowledge and most commonly financial investment. Inventors, scientists, artists, and entrepreneurs dedicate their time, effort, and resources to create a work or invention. Taking into consideration the characteristics of intellectual property, particularly its intangibility and non-rivalry, intellectual goods could be simply copied and adopted by other entities that avoided the initial investment leading to development of such goods. Unrestricted copying of intellectual achievements may give competitors of innovative entrepreneurs an unfair advantage, allowing them to benefit from someone else's investment without bearing the costs. The legal monopoly over creations gives the authors, inventors or investors an opportunity to make a fair return on their investments. The particular nature of intellectual goods required the development of a special system of rights tailored to each category of intellectual goods. Granting a monopoly over intellectual property encourages development and incites innovators to share their achievements with society.

On the other hand, the monopoly vested in the IPR proprietor is generally limited in time. When the given IPR elapses, for example due to the passage of time or failure to pay the relevant fees within the deadline, the protected good enters public domain and may be exploited by anyone.

Curiosities:

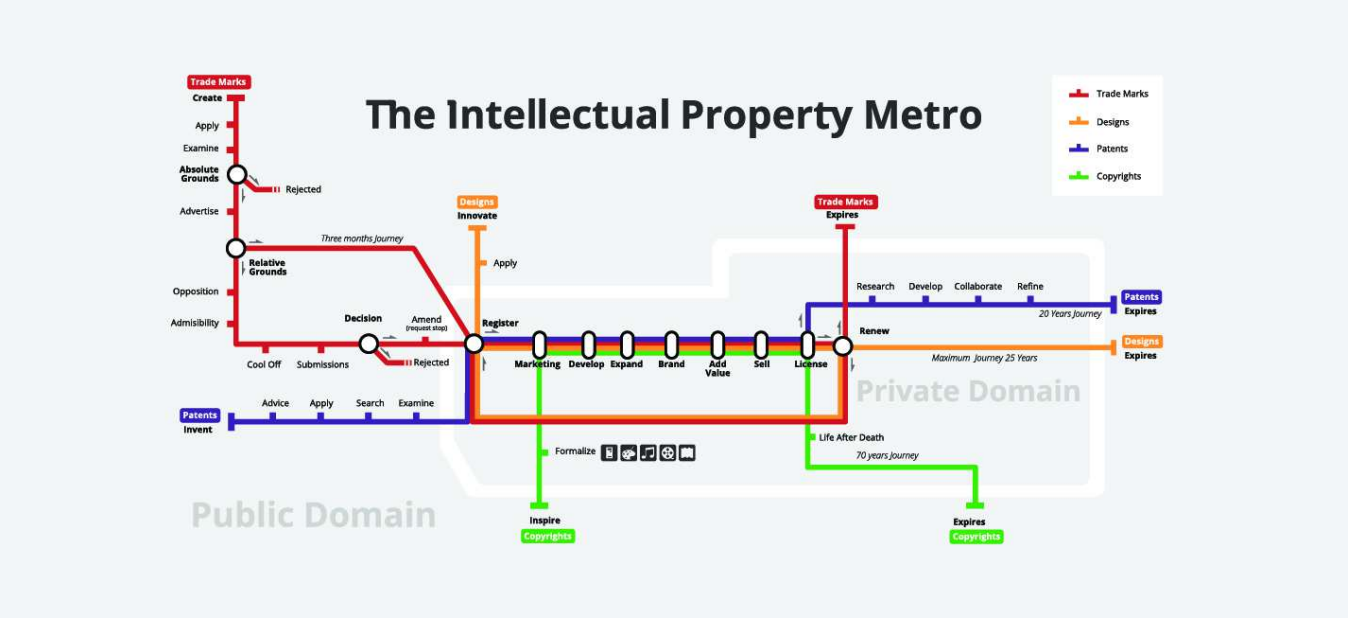
Did you know that the first authenticated instance of a royal patent-like grant was awarded by King Edward III of England to John Kemp in 1331? The grant gave a monopoly over woollen cloth weaving trade in England.

The first codification of a patent system is the Venetian Patent Statute, issued by the Senate of Venice in 1474.

The IPR system

Different intellectual property rights protect various types of intellectual goods. One complex product may be protected by a variety of IPRs.

For example, different parts of mobile phone (including software) may be protected under multiple laws such as patents, copyright, design rights, trademarks. One mobile may contain thousands of goods protected under intellectual property rights.



Source: EUIPO, https://mobile.x.com/EU_IPO/status/1546466835801030657

1.2.1 Patent

1). Subject matter of protection

Patents are granted for inventions that are new, involve an inventive step, and are industrially applicable. The notion of invention has not been positively defined by legislators; however, relevant legal acts usually contain a negative list of objects that are not considered inventions. These listed objects are excluded from patentability as such, which means that if the patent application concerns solely the listed object the patent will be refused. However, if the application also includes other features that have a technical character, the patent may still be granted.

The Article 52 of the European Patent Convention may be used as an example of non-inventions:

- discoveries, scientific theories and mathematical methods;
- aesthetic creations;
- schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
- presentations of information.

The list in non-exhaustive, which means that European Patent Office may consider another type of objects or activities as non-inventions excluded from patentability.

Moreover, even if a given development could be considered as invention, it cannot be patented if it falls under the scope of exceptions of patentability. Usually, a patent cannot be grated for:

- Inventions whose exploitation would be contrary to public order or morality;
- plant or animal varieties or essentially biological processes for the production of plants or animals (this exclusion does not apply to microbiological processes or the products thereof);
- methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body (this exclusion does not apply to products used in these methods).

Patentable invention

The Patent may be granted regardless of the field of technology that the invention concerns, as long as the invention has a technical character.

The invention must meet three prerequisites to be patentable:

- It is new, which means that the invention does not form part of the state of the art;
- It involves an inventive step, meaning it is not obvious to a person skilled in the art, considering to the state of the art;
- It is capable of industrial application.

Each of the patent claims is examined in the light of all three patentability conditions. This means that, if a given feature of the invention, described in a patent claim does not meet all the patentability criteria, it would fall out of the scope of the patent protection. In other words, the patent may still be granted, but the specific feature would not be protected. While describing patentability conditions, this document may refer to "invention" as a whole; however, this is a deliberate simplification to make the patentability requirements easier to explain.

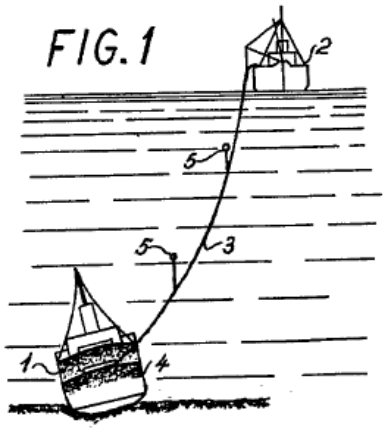
The patentability prerequisites require further consideration.

Novelty

An invention is considered new if it is not part of the state of the art.

The state of the art means the body of knowledge existing in the determined moment in time, namely the filing date (or priority date, where applicable), in the relevant field of technology. It encompasses everything that, before the priority date for obtaining a patent, has been made publicly available in any form, such as in written or oral form, by use, or display. State of the art includes any sources in any language and from any geographical location. There are no restrictions regarding the manner of presenting the information or limits regarding the age of the sources.

Example:



In 1966 a Danish inventor, Karl Kroyer, filed a patent application concerning a method for raising sunken or stranded vessels. The method involved introducing buoyant bodies, such as gas-containing polystyrene balls or pieces of cellular plastic material, into the interior of the vessel. The application was rejected as the examiners at the patent office discovered that a similar method for rising a sunken vessel had been used by Donald Duck and his nephews in the comic book from 1949.

Source: 4 Patent Prior Art Examples where Examiner found Best Results - GreyB

Therefore, **the state of art includes** not only scientific or sectoral publications, conference presentations, offered or marketed products, and use or demonstrations of the invention in any way, but **all available resources regardless of their type or nature**.

The invention is considered made available to the public when it is disclosed in a manner that enables a person skilled in the art, at the relevant date, to reproduce the invention.

Prior art includes information contained in earlier patent or utility model applications that claim priority, but have not yet been made public, provided they are published later as prescribed by law. An earlier application destroys the novelty of later applications if the earlier application is made public, with retroactive effect from its filing date.

Specific concept of novelty in pharmaceutical inventions - first and further medical use

First medical use

It is still possible to obtain a patent for a substance or composition that is already known (constitutes a part of the state of the art), but its medical use was previously unknown. Medical use means use in therapy, surgery, or diagnostic. If the substance or composition has already been used in any medical method, it could not be patented within this category.

Frther medical use

Second or further medical use is a category of inventions that may be patented even though the invention has been already known, and its medical use has already entered in the state of the art. A patent may still be granted for substance or composition if it has the ability to achieve a particular therapeutic effect that is novel and has an inventive step.

Inventive Step

Generally, the inventive step prerequisite is examined once the novelty of the invention is established. The invention is considered to involve an inventive step if it is not obvious to a person skilled in the art, taking into consideration the state of the art.

A person skilled in the art is a legal concept that refers to a model person. Such a person is a skilled practitioner in their field, possessing average knowledge and ability in the relevant technical field. However, the model person skilled in art lacks creativity and operates routinely.

If the invention is obvious to the person skilled in art, considering the priority date, the invention lacks an inventive step and therefore patent protection would be denied.

Industrial Applicability

An invention is deemed industrially applicable if a product can be produced or a process can be used, in any kind of industry, including agriculture. In other words, the invention has to be useful and possible to implement in practice.

Industry is understood very broadly for the purpose of this prerequisite. Some legal acts require indicating the manner of the industrial application of the invention in the patent application,

How is an invention described in the application?

An invention is described in the patent application by claims and description. Patent claims are vital for determining the scope of protection. Only the features expressed in the claims are protected under the patent. The claims are accompanied by a description, which is used to interpret the claims. It should be noted that features disclosed in the description that are

not contained in the patent claims are not protected. Such features enter the public domain. Moreover, the patent application contains an abstract, however, it is used solely as a tool for search purposes, and it cannot not be utilized for the interpretation of the claims.

Description of the invention

The description explains the invention. It presents prior art that may be useful for understanding the invention, together with indicating the relevant documents presenting prior art, especially patent specifications.

The description should disclose the invention in a manner that enables the identification of the technical problem and the solution implemented by the invention. The technical field to which the invention relates should be indicated. Only details necessary for elucidating the invention should be included in the description. If drawings are included in the patent application, they should be briefly described.

Sufficiency of disclosure is assessed based on the application, including the description, claims and drawings, and the indicated technical field.

Claims

The scope of a patent is defined by the claims included in the patent specification. The description of the invention and the drawings may be used to interpret the claims.

Claims are a crucial element of patent application as they determine the scope of the patent protection. A patent application must contain at least one claim. Claims should be formulated in a clear and concise manner and relate to technical features of the invention. Moreover, the way of expression of the claims is quite formalized.

Claims are used for the precise definition of the patent subject matter. They may be supported by the description of the invention.

Two basic categories of claims may be distinguished; product claims and process claims. The first category may refer to an apparatus, machine substances or compositions. Process claims refer to activities.

Biotechnological inventions concern a product consisting of or containing biological material or a method by which biological material is produced, processed, or used. Biological material means material that contains genetic information and is capable of self-reproduction or reproduction in a biological system. Biotechnological invention must meet the previously discussed patentability criteria: it should be new, involve an inventive step, and be industrially applicable.

2). Scope of protection

A patent is an exclusive right that gives its proprietor a monopoly over the commercial use of a patented invention. The patent holder may prevent any other entity from producing, offering, putting on the market, using, exporting, or importing the products in which the patented invention is implemented, or which is produced using the patented method, without their consent. A patent for a process includes the products directly obtained by that process.

Territorial scope

A patent has a strictly territorial character. It protects the invention on a specific territory, namely the territory of the country in which the patent has been granted. Obtaining patent protection for an invention in different countries at the same time was burdensome. However, based on international treaties, applicants can simplify the formalities in such situations. It is possible to file one application within an international procedure that enables to obtain a bundle of national patents, which are independent from each other. Such systems include for example the PCT (with 157 member countries), European Patent (39 member countries).

There is the possibility of obtaining a patent that is valid in a specific region covering the territory of several countries, such as the European patent with unitary effect (European Patent Office), OAPI patent (African Intellectual Property Organization), GCC patent (Gulf Cooperation Council Patent), and Eurasian patent (Eurasian Patent Office).

3). Duration of protection

A patent lasts for 20 years from the filing date of the application with the Patent Office. If the maintenance fees are not paid to the relevant patent office, the patent will lapse earlier.

4). Right holder

The inventor is entitled to obtain a patent for their invention. However, this right may be vested in another entity, for example, when the invention is created by an employee or under a commission contract. The vesting of the right to obtain a patent is subject to national legislation.

5). How to obtain a patent?

To obtain a patent, the inventor must disclose the invention in the patent application. The disclosure should be clear and detailed enough to allow a person skilled in the relevant field of technology to reproduce the invention. The application is later published in a patent register that is publicly available. After the patent elapses (usually 20 years) the invention enters public domain meaning it can be used commercially by anyone.

National patents

Patent laws vary to some extent between countries; however, the overall application procedure is generally similar and includes the following steps:

1) Application - The inventor, or other entitled entity, has to file an application with the relevant patent office;
2) Examination of the application – first verification whether application provides all required information and documents. If the application fulfils the formal requirements, it is accorded a date of filing.
3) Search report – it is an initial report on the state of art, and includes a list of relevant patent documents;
4) Publication – the application is usually published along with the search report, usually 18 months after the date of filing (or priority date, if claimed);
5) Substantive examination – the invention and the application are verified in the light of statutory requirements;
6) Decision – the patent office issues a decision for either granting the patent or rejection.

Patent application

Each applicable law defines the necessary elements of the patent application. The application is prepared on a special form and comprises the following elements:

- a request for the grant of a patent;
- a description of the invention;
- one or more claims;

- drawings, if the description or the claims refer to drawings;
- an abstract.

A request for the grant of a patent is usually required to be made on an appropriate form. The request includes the title of the invention, name of the inventor (s) and should define the entity (entities) that applies for a patent, its entitlement to the invention, representatives (if any).

Description – describes the invention and is used to interpret the claims. The Description should summarize prior art and identify the technical problem that the invention solves. Itis important to note that if some of the patent features are presented in the description but are not included in the claims, those features will not enjoy the protection.

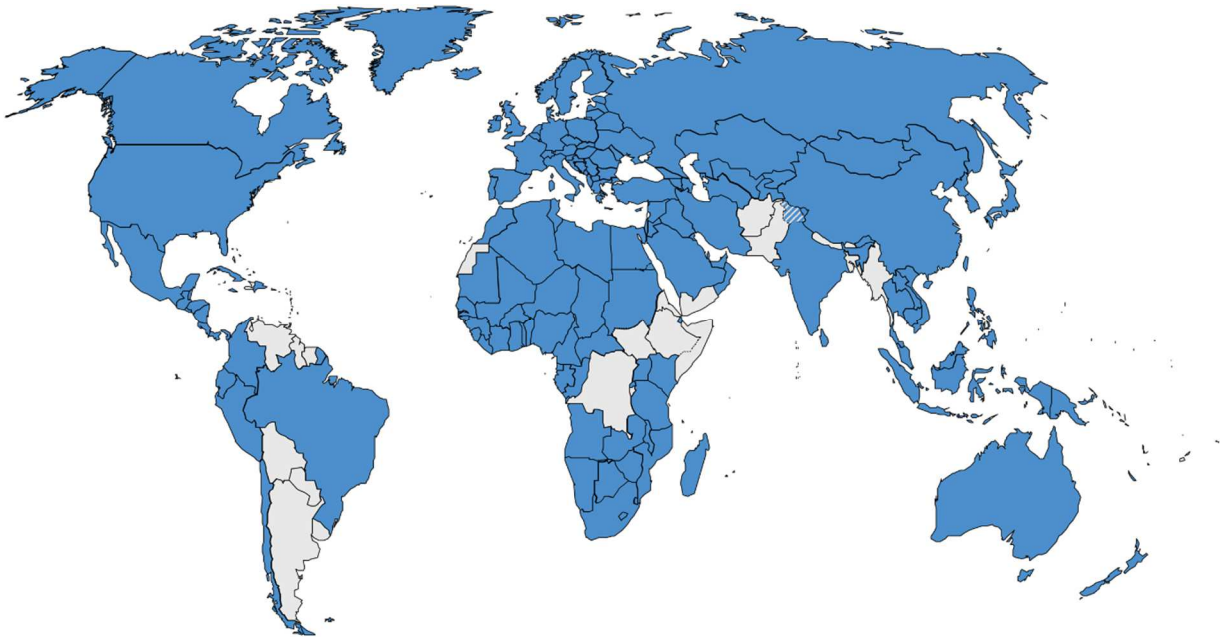
Claims are the core of the patent application. They define the subject matter of the application, and later of the patent.

Drawings usually are not an obligatory element of the application; however, they might be necessary to understand the invention. They are used to interpret the claims.

Abstract should provide brief information about the invention. It is used as a tool for search purposes, and it cannot not be utilized for the interpretation of the claims.

PCT – possibility to obtain patents in selected countries

The PCT is an international patent system administered by World Intellectual Property Organization under the Patent Cooperation Treaty. The system allows for obtaining patent protection in any (or all) of the signatory states chosen by the applicant by filing one application. The application may be filed, together with relevant fees, at a national patent office, European Patent Office or WIPO International Bureau. Aa a result of successful application a bundle of national patents is granted. Currently (2024), 157 countries are parties to the PCT.



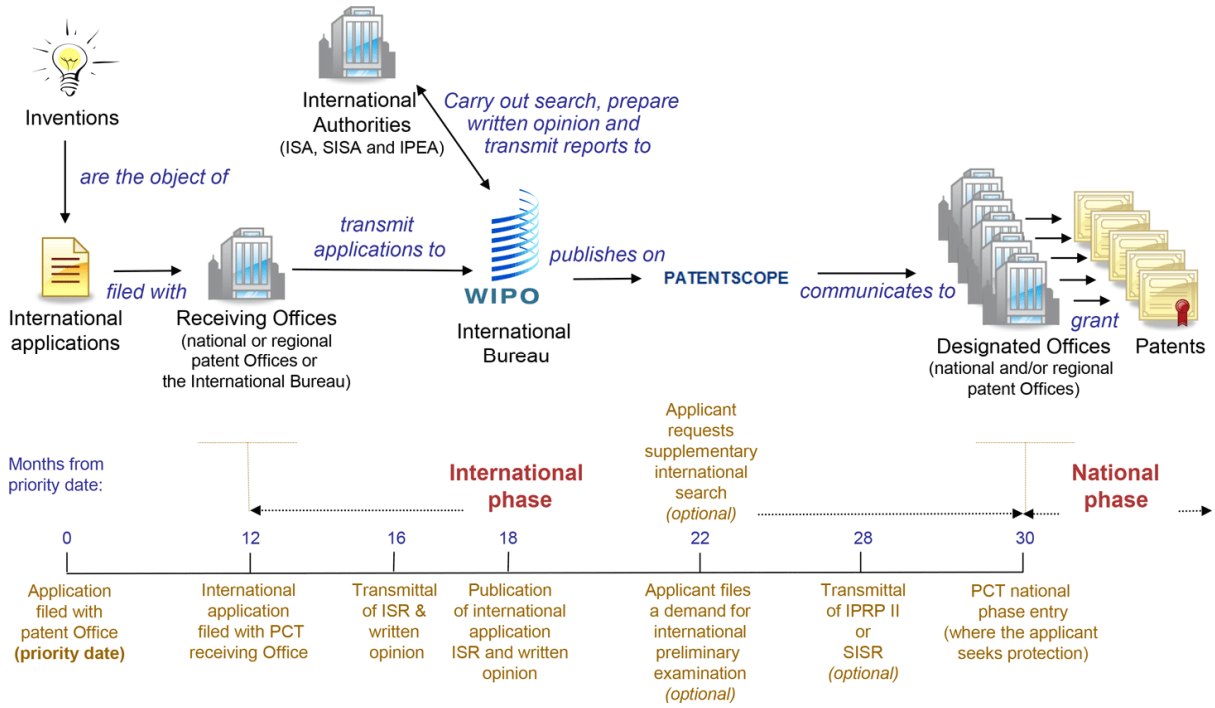
Source: https://www.wipo.int/pct/en/pct_contracting_states.html

The application procedure is divided into two phases – **international and national** (or regional).

> During the international phase, an international search report is produced by the international search authority (ISA) selected in the patent application. The search report presents published patent documents and literature relevant for patentability examination and is accompanied by an opinion on patentability. Based on the international search outcome, the applicant may amend the claims or even withdraw the application. The patent application and the search report are then (after 18 months from the priority date) published on PATENTSCOPE, WIPO's patent database. Optionally, the applicant may choose to conduct supplementary international search by another ISA, or an international preliminary examination. Those documents provide additional, in-depth analysis on patentability. Such information is valuable, in particular when the initial application was amended after the international search report. None of those documents are binding for national patent offices; however, if the applicant decides to transfer the rights to obtain the patent/patents, such additional documents may increase the value of those rights.

At the end of the international phase the applicant must select the countries in which they want to obtain protection. The deadline for entering the national phase is **30 months** from the priority date.

National or regional offices require payment of the relevant fees and sometimes translation of the application. In the national phase the application is examined by each of the national or regional patent offices that have been selected in the application. The offices assess the application under the relevant national (regional) law taking into consideration the results of the search received from WIPO.

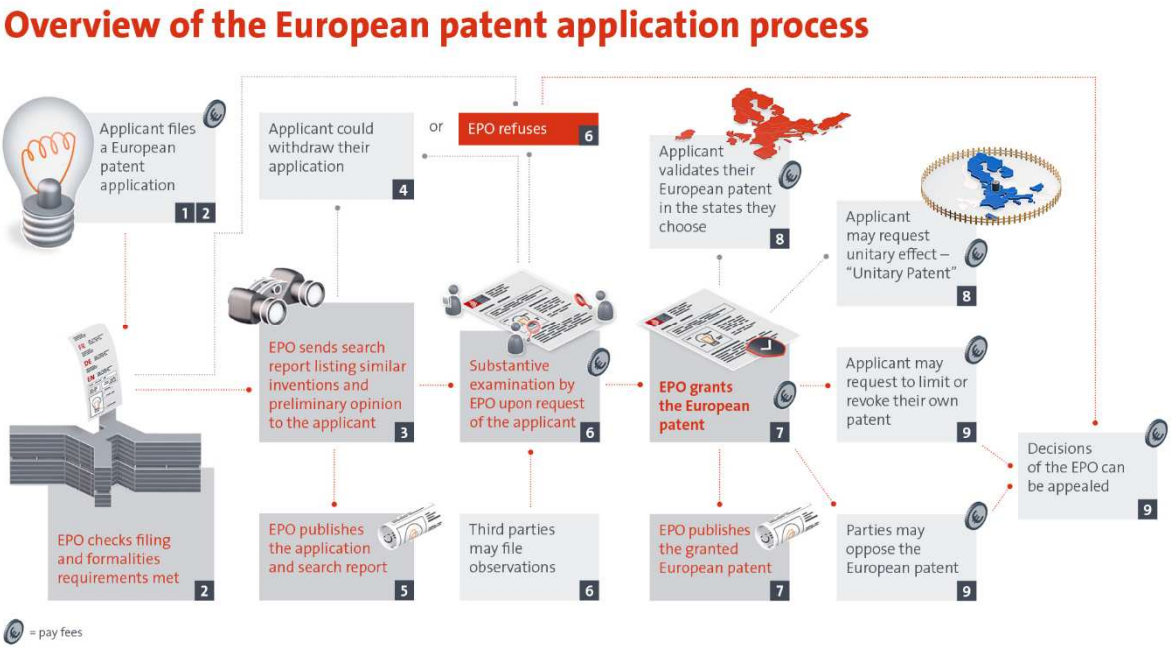


Source: PCT FAQs (wipo.int)

European patent & European patent with the unitary effect

The European Patent procedure, like the PCT, enables the filing of a single application which may result in the granting of a bundle of independent national patents. However, within the European Patent procedure, the applicant may also request unitary effect for their patent. Contrary to the PCT outcome, a European patent with the unitary effect is a single patent, automatically valid in all EU member states that participate in enhanced co-operation and have ratified the Agreement on a Unified Patent Court (UPC). Ratification of the UPC Agreement is crucial for the unitary system, because the unitary effect requires unified implementation of the material law and unitary court proceedings. Therefore, a single international Unified Patent Court has jurisdiction over Unitary Patents, including

infringement (violation) and invalidation of the patent. Currently (as of September 2024), the Unitary Patent has effect in 18 Member States; however, it is expected that more EU Members States will ratify the Agreement on a Unified Patent Court and fully join the system.



Source: https://www.epo.org/en/new-to-patents/how-to-apply-for-a-patent

The standard procedure is initiated by filing an application with the European Patent Office (directly or through a national patent office) and paying the initial fees. The application undergoes formal verification, after which EPO sends the search report and an initial opinion on meeting the patentability requirements. Upon receipt of the search report along with the opinion, the applicant may decide to pursue the application. If, in light of the search report and opinion, the likelihood of obtaining a patent is low, the application may be withdrawn before its publication. If the application is not withdrawn, it is published within 18 months of the filing date (or priority date, if claimed). The application will be available in European Patent Bulletin, Espacenet (EPO patent database), and the European Patent Register.

If the applicant decides to continue the procedure, they will have to request the substantive examination and pay the examination fee. After the patent application is assessed, the EPO issues a decision on grating the European Patent or refuse the application. The latter decision can be appealed. The examination usually takes 3-4 years.

If the patent is granted, the applicant may designate the countries (from 39 European Patent Organization Member States) in which the patent shall be validated in order to obtain a national patent. The request should be filed within 3 months of the receipt of the EPO's decision. The European Patent must be validated under national law in each designated country, which requires payment of relevant fees.

At the same time the applicant may decide to request the unitary effect. If the request is successful, the patent will have a unitary effect in all the 18 courtiers which participate in the Unitary Patent System. The request should be filed within 1 month of the publication of the EPO's decision in the European Patent Bulletin. The terms for filing a validation request and unitary effect request are independent. A request for unitary effect does not exclude the possibility to validate the European Patent in selected states (for example, those for which the unitary effect does not apply, such as Poland, Spain, and the UK).

Patent rights in Greece

Law 1733/1987 on Know-How Transfer, Inventions and Technological Innovation, as amended and valid today, is the main patent law followed by a number of implementing law provisions, presidential decrees, ministerial decisions as well as ratification acts for the incorporation of European law and international treaties into Greek law. These laws align with European Union standards, ensuring the protection of intellectual property. Greece is also a signatory to key international treaties, including the World Intellectual Property Organization (WIPO), the Paris Convention for the Protection of Industrial Property, the European Patent Convention, the Washington Patent Cooperation Treaty, and the Bern Copyright Convention.

The Industrial Property Organization (OBI), based in Athens, is the competent authority responsible for administering patents, Supplementary Protection Certificates (SPCs), designs, utility models, and relevant intellectual property rights.

Patentability Requirements**:**

Greek patent law establishes that an invention must meet three essential criteria to be eligible for patent protection:

- Novelty: The invention must be new, meaning it has not been disclosed to the public in any form prior to the filing date of the patent application.
- Inventive Step: The invention must involve an inventive step, signifying that it is not obvious to a person skilled in the relevant technical field.

- Industrial Applicability: The invention must be capable of being used in some form of industry, which includes agriculture.

Inventions can relate to products, production methods, or processes that solve a technical problem. This includes improvements to existing products or methods. Additionally, inventions must provide a practical, technical solution that can be implemented in an industrial context.

Application Process

The patent registration process in Greece is managed by the OBI. The process involves several steps:

1. **Pre-Filing Search (Optional):** Filing a request for a preliminary search by OBI. Conducting a preliminary search can help determine if similar prior art exists. This is not mandatory, but this may identify potentially relevant prior art.
2. **Filing the Application:** Patent applications must be submitted to the OBI either online or physically. The application must include:
    - **Applicant Information**: Name (or trade name if a legal entity), nationality, residence or seat, and address of the applicant.
    - **Invention Details**: A detailed description of the invention, outlining its technical characteristics and functionality.
    - **Claims**: These define the scope of protection sought for the invention.
    - **Abstract**: A concise summary of the invention.
    - **Drawings**: Any necessary technical drawings to support the description and claims.
    - **Request for Grant**: A formal request for the granting of a patent.

The official language for patent applications is Greek. Applications can initially be submitted in English, French, or German, but a Greek translation must be provided within four months.

Examination and Grant:

1. **Formal Examination:** After filing, the OBI conducts a formal review of the application to ensure it meets all procedural requirements. The applicant is often invited to correct formal deficiencies within four (4) months from application. No additional material or substantial amendments can be added during this stage.

2. **Search Report:** If the applicant pays the search fee within four months from the filing date of the application, OBI prepares a search report. This report includes information about prior art relevant to assessing the novelty and inventive step of the invention. However, if the fee is not paid on time, the patent application is automatically converted into an application for a utility model certificate. The search report is sent to the applicant, often after 10 or even 12 months from application. The applicant has three months to provide comments. Based on these comments, OBI prepares a final search report that considers all relevant prior art for assessing the invention's patentability. The search report and the final search report have an informative character. Under the Greek system, no examination takes place and everyone who fulfils the formal requirements gets a patent.

3. **Publication**: Patent applications are made publicly available 18 months after the filing date or priority date. However, if the patent is granted before this period, it is published immediately upon grant.

4. **Granting of Patent:** The OBI grants a patent after the completion of the examination process. Patents are typically granted within 12–15 months of filing if all formalities are satisfied. The granted patent is recorded in the Patents Register, and a summary is published in the Industrial Property Bulletin.

Patents in Greece are valid for 20 years from the filing date of the respective application, provided that annual maintenance fees are paid. The duration of a patent can be extended by up to five years through a Supplementary Protection Certificate (SPC) for medicinal and plant protection products.

The cost structure for patent applications includes a €50 filing fee, a €150 patent granting fee, and an annual fee of €20 starting from the third year. This annual fee increases progressively: it reaches €600 per year starting from the 15th year of protection, and €1,100 in the 20th year, which is also the year the patent expires.

In Greece, patent holders possess exclusive rights over their inventions, which include the authority to produce, use, sell, offer for sale, license, or otherwise exploit the patented product or process. These exclusive rights extend to both products and manufacturing processes, as well as their uses or applications. Additionally, patent holders can prevent unauthorized third parties from making, using, or importing the patented invention.

Patent rights in Poland

Subject matter of protection

In Poland, patents are granted, for inventions that cumulatively meet three conditions: they are novel, involve an inventive step, and are susceptible of industrial application, regardless of the field of technology.

The third condition means that an invention is considered susceptible of industrial application if, according to the invention, a product may be manufactured or a process may be used, in a technical sense, in any kind of industrial activity, including agriculture.

The following are not considered inventions: scientific discoveries, mathematical theories, aesthetic creations, plans and methods for mental or commercial activities, and computer programs as such.

There are several categories of inventions that may not be patented:

1. inventions contrary to public policy or morality;
3. plant varieties and animal breeds, and essentially biological processes for the breeding of plants or animals, though this exclusion does not apply to microbiological or other technical processes, nor to products obtained by such processes;
4. methods of treatment of humans or animals by surgery or therapy, as well as diagnostic methods, though this exclusion does not apply to products, in particular substances or mixtures used in diagnosis or treatment.

Scope of protection

The holder of a patent acquires the right to exploit the invention for profit or in a professional capacity throughout the territory of the Republic of Poland. This includes the exclusive right to manufacture, use, offer for sale, sell, or import a product incorporating the invention, as well as to use a patented process.

The inventor (a natural person) has several rights related to their invention:

- the right to be named as the inventor in the patent application, patent specification, and other official documents;
- the right to be mentioned as the inventor in publications relating to the invention;

- the right to remuneration where another entity (for example employer or commissioner) exploits the invention or holds the right to patent it.

Duration of protection

The term of a patent is 20 years from the date of filing of the patent application with the Patent Office of the Republic of Poland, or from the priority date, if claimed.

Right holder

The right to obtain a patent belongs in principle to:

1. The inventor - as the primary and default right holder;
2. The employer - where the invention was made by an employee in the course of their employment duties, unless the employment contract provides otherwise.
3. The comissioning party - where the invention was made by an individual under a civil law contract (e.g. a contract for specific work), unless the contract provides otherwise.

How to apply?

A patent application must include: a request containing at least the identification of the applicant, a description of the subject matter of the application, and a request for the grant of a patent or an additional patent. In addition, the application must contain a description of the invention, patent claims, drawings (if neccssary) and an abstract.

The procedure comprises the following stages:

1. First, the filing date is assigned;
2. The invention is then classified and a state-of-the-art report is prepared;
3. Next a formal examination is conducted;
4. The application is then published in the Bulletin of the Patent Office after 18 months from the priority date, at which point third parties may submit observations;
5. A substantive examination is then conducted, during which the Patent Office assesses whether the invention meets the conditions required for the grant of a patent

6. Finally, if all conditions are met, the Patent Office issues a decision granting the patent, which is recorded in the Patent Register and confirmed by the issue of a patent document.

Following the grant of a patent, any person may file an opposition within 6 months of the announcement of the grant.

Where and in what form to file the application?

The national procedure is initiated by filing a request with the Patent Office of the Republic of Poland (UPRP).

An application may be filed in two ways:

1. In paper form - the filing fee is PLN 550;
2. In electronic form - the filing fee is PLN 500. Electronic applications are handled via the Electronic Services Platform of the Patent Office, which enables the filing of a patent application online through to receipt of formal confirmation of the application.

Additional fees are charged for each page exceeding 20 pages of description, claims, and drawings.

Patent rights in Romania

Patent rights in Romania are governed by Law No. 64/1991 on patents, which was republished in 2014. This law ensures that inventors have their rights to inventions recognized and protected throughout the territory of Romania. The patent process is overseen by the State Office for Inventions and Trademarks (OSIM), the national authority responsible for granting patents.

Any person who has duly filed a patent application in any state party to the Paris Convention or a member state of the World Trade Organization (WTO) benefits from a right of priority for a period of 12 months, calculated from the filing date of the earlier application, for the purpose of filing a subsequent patent application in Romania for the same invention (Article 19 of Law No. 64/91 on patents, republished in 2014). Romanian applicants also enjoy the same right of priority if they have made a valid filing in Romania, allowing them to make a subsequent filing in any of the member states of the convention or the above-mentioned

organization. They can thus invoke, within the 12-month priority period, the filing date obtained in Romania, at OSIM.

1.2.2 Copyright

Copyright is an exclusive right that protects works. Copyright protection arises automatically regardless of the value of the work (including banal works), its purpose and does not require any formalities.

1). Subject matter of protection

It should be noted is that copyright protects solely the form of expression; therefore, ideas presented in the work do not fall under the scope of the protection. Copyright does not protect discoveries, ideas, procedures, methods, and operating principles, or mathematical concepts.

Example:

Source:
https://www.sciencemagazinedigital.org/sciencemagazine/04_june_2021/MobilePagedReplica.action?pm=2&folio=Cover#pg1

The conceptual layer of the work is not protected under copyright. The research results presented in a scientific article would not benefit from copyright protection. Only the form in which the author expresses the scientific achievements is protected by copyright. The concepts presented in the paper may be protected in another IPR regime, for example under patent. A publication destroys the novelty of an invention or utility model. If research results may be protected under industrial property rights such protection should be sought prior to the publication of the scientific paper (or other form of dissemination). Filing an application for a patent is enough to enable the publication, the applicant does not have to wait for the grant of the patent. However, if the dissemination occurs before publication of the patent application, the

possibility to amend or withdraw the application would be limited or excluded. It is crucial to develop a deliberate, strategic approach to the dissemination of the research results.

Each national law provides legal definition of a work. At the EU level, there is no unified legal definition of a work. However, the case law of the Court of Justice of the European Union, which is binding for Member States, provides an autonomous EU concept of work. The work should be original in the sense that it reflects the author‘s personality. The work is a result of free and creative choices of the author, who leaves an individual, personal imprint on the work. This means that the work is the author’s own intellectual effort and therefore has a personal touch. The author expresses themselves by making free and creative choices that form the work.

Examples of works:

- Literary, journalistic, and scientific works, such as poems, novels, and articles
- Computer programs
- Paintings, drawings, sculptures, and other visual art
- Choreographic works
- Photographs
- Industrial designs
- Cinematographic works
- Architectural, architectural-urban, and urban planning works
- Musical and word-music compositions

2). Scope of protection

Copyright has dual nature and protects work in two aspects: economic and personal.

Economic (property) rights grant the copyright holder a monopoly for the use of the work and enable monetizing the work. The copyright holder is exclusively entitled to exploit the work. Economic rights encompass the right of reproduction, right of distribution, right of communication to the public, rental and lending rights and the right to exploit derivative works. Economic rights are transferrable, might be licensed, constitute an in-kind contribution to a company, or serve as collateral.

Moral rights, on the other hand, protect the author's personal bond with the work. They focus on the personal and reputational interests of the author. They are not transferable and are everlasting. The catalogue of moral rights varies in different Member States but usually includes the right of the authorship of the work, the right to attribution of the work (with the author's name or pseudonym, or to make it available anonymously), and the right to integrity of the work.

3). Duration of protection

The requirements for a work to arise differ across jurisdictions. In some legal systems copyright protection arises upon establishment of a work. It means that the work has to be externalised in any form perceptible to persons other than the author. No material medium is required, therefore an improvised speech or live performance may attract copyright protection.

According to some national laws, copyright arises from the moment of fixation of the work in some material form. This means that the work should be captured in any material form in a way that enables perception of the work, its reproduction or communication. For example, the work may be saved in a digital file, written on paper, recorded on audio or video. The work does not have to be completed, unfinished works are also protected. The fixation requirement can be met even if the work does not have a permanent nature – for example an ice sculpture or flower arrangement.

In the EU, economic rights last for the author's lifetime and 70 years after their death. Moral rights, however, are perpetual and do not expire.

4). Right holder

Copyright protection extends to works created by any person, regardless of legal capacity. This includes works authored by minors or individuals with limited legal capacity.

Generally, the author is the rights holder of both economic and moral rights to the work they create. However, in certain situations, economic rights may be vested in another entity, such as an employer. These cases are governed by national laws, which may differ from country to country.

5). How to obtain protection?

Copyright protection arises automatically and does not require any formalities. In practice, a copyright notice is often attached to a copy of a work to inform the public about the copyright holder or existence of the copyright. For example, the © symbol, along with the year of creation and indication of the right holder, is commonly used.

Copyright in Greece

Copyright and related rights are protected under Law No. 2121/1993 on Copyright, Related Rights and Cultural Matters (Copyright Law), which has been amended several times to align with European Union directives.

Protected Works: Copyright protection applies to any original intellectual creation in the literary, artistic, or scientific domain, expressed in any form. This includes written and spoken texts, musical compositions, theatrical works, choreographies, illustrations and audio-visual works, visual arts (such as drawings, paintings, and sculptures), artworks, works of applied arts, architectural works, photographs, software, and databases. Originality in copyright law is understood as the product of the personal contribution of the author, which grants the work a certain degree of individuality that distinguishes it from other works.

Additionally, the law provides protections for specific types of work, including software and databases. Software, for instance, is treated as a literary work under copyright law, and databases may receive sui generis protection if they are the result of an intellectual creation, with protections extending to the selection and arrangement of their contents.

The Copyright Law is, to a large extent, influenced by the French legal doctrine of droit d'auteur and protects the author's both moral and economic rights as two independent bundles of rights.

Moral Rights: Creators have moral rights that are perpetual, inalienable, and non-transferable. These include the right to be recognized as the creator of the work (right of paternity) and the right to object to any distortion or modification of the work that would harm the creator's reputation (right of integrity). Additionally, creators hold the right of rights of divulgation, which gives them control over the release of their work, the right of access,

ensuring the work remains available to the public, and the right of withdrawal, allowing the creator to remove the work from circulation if desired.

Economic rights: Economic rights are generally associated with the commercial exploitation of a work of authorship, enabling creators to control how their works are used for financial gain. These rights allow creators to exploit their works in specific ways, including:

- **Reproduction Right:** The right to authorize or prohibit the reproduction of the work.
- **Distribution Right:** The right to authorize or prohibit the distribution of copies of the work.
- **Public Performance Right:** The right to authorize or prohibit the public performance of the work.
- **Broadcasting Right:** The right to authorize or prohibit the broadcasting of the work.

In addition, these rights encompass the right of recordal, translation, adaptation, and rental. Creators also hold the right to import copies of their works. Public lending of works is permitted to libraries, typically for a reasonable fee, which is paid by the libraries to collective management organizations representing the authors.

Under the Copyright Law, moral rights cannot, in principle, be waived or transferred, but they can be inherited. However, authors are generally entitled to assign (in effect transfer) or license their economic rights in respect of a certain work of authorship. Authors reserve the right to revoke such license or transfer if their works remain exploited within a reasonable amount of time and are entitled to receive comprehensive information on the exploitation of their works (transparency obligation) at least once a year.

Related rights: are those deriving from or associated with performers, producers of phonograms and audiovisual works, broadcasting organizations and publishers of printed matter. The protection regime of the related rights is based on the concept of authorization, which is the exclusive and absolute right of rights holders to allow or prohibit certain acts specified in the law in a restrictive manner. However, in certain circumstances, related rights may constitute only a legal obligation for payment of an equitable remuneration to the rights holder, in the sense that no authorization needs to be sought. Law No. 4481/2017 sets out the principles of collective management of copyright and related rights in Greece.

Protection of Copyrights: In Greece, copyright protection is automatic upon the creation of a work. No formal registration is required for protection to apply. However, creators may opt

to use services like the Hellenic Copyright Organization (OPI) to obtain a timestamp, which can serve as proof of the creation date. This provides additional security for the creator's claim to the work. Copyright law in Greece applies to works of authorship that are original, including literary, artistic, scientific, and other intellectual creations expressed in any form.

Finally, authors also retain a resale right, allowing them to claim royalties when their works are resold by art market professionals.

Duration of Protection: The duration of copyright protection in Greece generally lasts for the lifetime of the creator, plus an additional 70 years after their death. This applies to most works, including literary and artistic works. For works of joint authorship, the protection lasts for 70 years after the death of the last surviving author. Certain works, such as anonymous or pseudonymous works, and audiovisual works, may have specific duration rules. For example, visual artwork is protected until the expiration of its copyright term, after which its reproduction is no longer covered by copyright protection unless it meets the originality criterion on its own. This protection period ensures that creators and their heirs can benefit economically from the works for a significant time.

Limitations and Exceptions: Greek copyright law recognizes several limitations and exceptions to ensure a balance between the rights of creators and the public interest. For example, the law permits fair use for purposes like private study, research, criticism, and news reporting. These exceptions are intended to facilitate the use of copyrighted material in a way that benefits society without unduly restricting the creator's rights.

Copyright in Poland

Subject matter of protection

Polish law on copyright and neighbouring rights defines a work as any manifestation of creative activity with an individual character, expressed in any form, regardless of its value, purpose, or manner of expression. Creative activity is carried out by making free and creative choices regarding the manner of expression, and it can only be performed by a natural person, regardless of their legal capacity.

Individual character is a core concept of the copyright system in Poland. It means that the author imprints their personality onto the work, and in this way, the work reflects the author's individuality.

Additionally, the work must be expressed in such a way that a recipient has the opportunity to become familiar with it. Copyright protects only the form of expression, not the ideas or concepts underlying the work.

Scope of protection

Economic rights grant the rights holder a monopoly over the use of a work in specific ways, referred to as fields of exploitation. These fields are listed in the Law and include, in particular:

- reproduction and fixation of the work – Producing copies of the work using a specific technique, including printing, reprography, magnetic recording, and digital techniques;
- distribution of the original or copies of the work – Placing the original or copies of the work into circulation, lending, or renting them;
- public dissemination of the work in ways other than distribution – This includes public performance, exhibition, display, playback, broadcasting, and rebroadcasting, as well as making the work publicly available in such a way that anyone can access it at a place and time of their choosing.

Moral rights include:

- authorship of the work;
- attribute the work to their name or pseudonym, or to make it available anonymously;
- preserve the integrity of the work's content and form, and ensure its fair use;
- decide on the first public disclosure of the work;
- supervise the manner in which the work is used.

Duration of protection

In Poland, protection arises from the moment od establishment of a work. Economic rights last for the author's lifetime and 70 years after their death, whereas moral rights are perpetual.

Right holder

Type of work	The owner of the copyright
Independent work created by the author (a natural person)	The author
Work created under the employment contract	Employer, unless otherwise agreed in the employment agreement
Work created under a commission contract	Depends on the contractual arrangements – the author owns the copyright in the commissioned work unless otherwise agreed. It is necessary that the transfer agreement is made in writing.
Joint works	Joint ownership of the coauthors.
Collective works	Each author/owner has economic rights to separate works, however, if the arrangement of the separate works itself meets the copyright criteria, the author of such collective work is entitled to the copyright.
Derivative works	Separate copyright to the derivative work is vested in its author, however, the derivative work cannot be exploited or the copyright. to the derivative work cannot be disposed of unless the permission of the author of the original work is given.
Scientific works (a specific provision)	As an exception from the general rule governing the copyright ownership of the works created under employment contract, the author is the copyright owner, however, the research institution has priority to publish the scientific work.

Copyright in Romania

In Romania, copyright law (*drept de autor*) is defined by the Law No. 8/1996 on authors rights and related rights, as republished in 2018, which currently implements European copyright law (directives).[1] Copyright is acquired irrespective of formalities and normally belongs to the

natural person/s who created the protected work. A protected work is created if the work is the author's own intellectual creation.[2]

Works protected by copyright

According to chapter III (Object of copyright) of the Law No. 8/1996 on authors rights and related rights,[4]https://en.wikipedia.org/wiki/Copyright_law_of_Romania#cite_note-:1-4 any original works (creation of human mind) in the literary, artistic or scientific fields, whatever the mode of creation, mode or form of expression, and regardless of their value and purpose, are protected by copyright.

The article 7 of the Law No. 8/1996 on authors rights and related rights[4] https://en.wikipedia.org/wiki/Copyright_law_of_Romania#cite_note-:1-4 provides a non-exhaustive list of works protected by copyright, such as:

1. literary and publicist writings, conferences, sermons, pleadings, lectures and any other written or oral works, as well as computer programs;
2. scientific, written or oral works such as communications, studies, university courses, school textbooks, scientific projects and documentation;
3. musical compositions with or without text; d) dramatic, dramatic and musical works, choreographic works and pantomime;
4. cinematographic works, as well as any other audio visual works;
5. photographic works, as well as any other works expressed by an analogue process of photography;
6. works of graphic or plastic art, such as sculpture, painting, engraving, lithography, monumental art, scenography, tapestry, ceramics, glass and metal, drawings, designs and other works of art intended for practical use;
7. architectural works, including drawings, layouts and graphic works that make up architectural projects;
8. plastic works, maps and drawings in the field of topography, geography and science in general.

Like other EU civil law jurisdictions, Romanian copyright law recognises two types of rights: moral rights and patrimonial rights.[3]

Moral rights

1. the right to decide if, how and when a work is brought to public knowledge;
2. the right to claim recognition as author of the work;
3. the right to decide the name under which the work is brought to public knowledge;

4. the right to claim the observance of the integrity of the work and to oppose any change or other interference with the work that damages the author's honour or reputation; and
5. the right to withdraw the work.

These rights cannot be waived or transferred. After the author's death, the rights under (1), (2) and (4) above are exercised by heirs, for an unlimited period of time.[3]

Patrimonial rights

1. reproduce and distribute the work;
2. import in order to commercialise on the internal market copies of the work made with the author's consent;
3. lease or lend the work;
4. communicate it to the public, directly or indirectly, including by making it available for the public to have access to at any time and in any place; and
5. broadcast the work, transmit it by cable or create derivative works thereof.

In addition, the author of a graphic, plastic art or photographic work has a resale right, which entitles him or her to receive a percentage of the price when the work makes the object of a reselling operation in which an art dealer participates as seller, buyer or agent.[3]

Author

According to chapter 2 (Subjects of copyright) of the Law No. 8/1996 on authors rights and related rights,[4] the Author is the natural person or persons who created the work. It is presumed to be the author the person under whose name the work was first brought to public knowledge. When the work has been made public in anonymous form or under a pseudonym that does not allow the identification of the author, the copyright shall be exercised by the natural or legal person making it public with the consent of the author, as long as he does not disclose his identity. The copyright of the joint work belongs to its co-authors, one of which may be the principal author, under the terms of this law.

Copyright formalities

In Romania, there is no requirement for a copyright notice in order to obtain copyright protection, as original works are automatically protected by copyright as of their creation. However, the author and other copyright holders are entitled to place on their works a copyright notice consisting of the letter C in a circle together with their name, and the place and year of the first publication. In cases where such a copyright notice is displayed, there is

a presumption that the work is copyright protected in favour of the person using the copyright notice, until otherwise proven.[3]

Duration of copyright protection

Duration of copyright protection is defined by chapter V (Object of copyright) of the Law No. 8/1996 on authors rights and related rights.[4] The general rule is that the patrimonial rights of the author last for seventy (70) years after his or her death. If there are no heirs, the exercise of these rights rests with the collective management body mandated during the lifetime by the author or, in the absence of a mandate, by the collective management body with the largest number of members in the field of creation.

Copyright infringement

Holders of copyright or related rights can file for infringement when there is:

- Unauthorised use of their works (by reproduction, distribution, loan, lease, communication to the public (including making available), importation, broadcasting, retransmission by cable networks or by making derivative works).
- Infringement of moral rights (first publication, attribution, right to choose name for publication, right to maintain integrity of the work, and right to retract the work).
- Infringement of the droit de suite (right to equitable remuneration).[2]

1.2.3 Rights Governing Utility models

Rights governing utility models are not harmonized internationally and remain within the national domain. Definitions of utility models depend on the national legislation and vary among the countries.

The nomenclature of rights varies in different courtiers (utility model, small patent, utility certificate). Moreover, not all countries provide protection for utility models. For example, United Kingdom, Luxembourg and Sweden has not adopted measures to protect such developments.

Generally, the conditions for obtaining protection for utility models are less stringent for patents. The costs of application are usually lower; however, the duration of protection is significantly shorter than patent protection. Utility models protection may constitute a less expensive alternative to patent protection or a tool to protect less creative developments.

Utility models in Greece

Utility models in Greece are regulated by Greek Patent Law No. 1733/1987, titled "Technology Transfer, Inventions, and Technological Innovations," which has been amended by various subsequent laws. A utility certificate is granted by the OBI with a view to protecting a utility model. This particular certificate awards an intermediate stage of protection between a patent and a design. A utility certificate is issued for any three-dimensional object with a defined shape and form, such as a tool, an instrument, a device, a utensil or an accessory, that qualifies as new, industrially applicable and capable of providing a solution to a technical problem.

According to settled case law, utility models should be new creations (i.e., beyond state of the art) of the human mind, included in a tangible movable object, capable of giving a solution to a technical problem, and proposed as novel and industrially applicable, in the same manner as inventions. In a utility model, the inventive step is not required to be of the same level as in the case of an invention, for which a patent is granted. In this respect, inventions with a minimum or no inventive step that do not qualify as patents may qualify for a utility certificate.

Application Process: The process for filing a utility model application with the Hellenic Industrial Property Organization (OBI) is structured into the following steps:

- **Preparation and Filing of Application:** The applicant must prepare in duplicate the required application documents, including a completed and signed application form available at OBI or online at www.obi.gr, a detailed written description explaining the object and its functionality, drawings (if applicable) illustrating the object, claims that clearly and precisely define the object's technical features (with at least one main claim required at the time of filing), and an abstract summarizing the key technical aspects of the object. Filing of all the application documents (or at least the application form, written description, and claims) has been entirely electronic since April 15, 2019, through OBI's portal (efiling.obi.gr) by the applicant or their agent (lawyer). The filing fee must also be paid at this stage to proceed.
- **Submission of Supplementary Documents:** If required, supplementary documents (e.g., power of attorney, additional legal documents, or corrections) must be submitted electronically within 4 months from the filing date. Applicants may also need to address corrections requested by the formalities officer or examiner. A letter

detailing these corrections is sent to the applicant, their patent agent, or representative.

- **Completeness Check:** On the completion of the 4-month period from the filing date, the application is checked for completeness (i.e. necessary documents/fees).
  - If the application is complete, then the utility model certificate is granted, provided that the respective fee is paid.
  - If the application is not complete, then it is withdrawn.
  - If the application claims priority from an industrial design application, the application for a utility model should be filed within 6 months from the application of the design.
- **No Examination for Novelty or Applicability:** The OBI does not conduct a substantive examination to verify the novelty or industrial applicability of the utility model. These criteria are the applicant's responsibility.
- **Publication of the Application:** The utility model application is published 18 months after the filing date (or priority date). If the certificate is granted before the 18-month period, it is published shortly after granting.
- **Granting of Certificate:** Once all requirements are met, the utility model certificate is granted when the granting fee is paid. There is no time limit for this payment.

Duration and Maintenance:

- **Protection Period:** Utility models are protected for 7 years from the filing date.
- **Renewal Fees:** Annual renewal fees are required starting from the third year. The fees increase progressively each year.

Rights Conferred: The holder of a utility model has the exclusive right to produce, use, sell, and generally exploit the three-dimensional object in Greece. This right excludes any third party from exploiting the same invention.

Cost:

- **Filing Fee:** The official fee for filing a utility model application is €50.
- **Publication Fee:** The publication fee is €100.
- **Renewal Fees:** The renewal fees start at €20 for the third year and increase each subsequent year.

Utility models in Poland

A utility model is a new and useful solution of a technical nature, relating to the shape, structure, or combination of an object of a permanent form. The requirements of novelty and industrial applicability, which constitute patentability requirements, are applicable to utility models. In Poland, the right may be granted solely for a product, not a process.

It is worth noting that the inventive step condition is not required in order to obtain protection for utility model.

Utility models that fulfil the prerequisites are granted protection. Protection is an exclusive right to use a utility model for profit or professional purposes throughout Poland. The right lasts ten years from the date of filing the utility model application with the Patent Office.

How to obtain a utility model protection

A utility model application is filed with the Polish Patent Office. The procedure is very similar to that for patents, and the provisions regarding patent applications are applied accordingly to utility model application. The application is made on a special form and contains all the elements required for a patent application.

The application undergoes formal and substantive examination. If all the conditions for protection are met, the Office issues a decision on granting the protection.

Utility models in Romania

Utility models shall be filed in Romania in accordance with the Law No 350/2007 on utility models, as republished in 2014 and the Implementing Regulations thereto.

Under Art.1 para (1) of the Law No 350/2007, a utility model shall protect any technical invention, provided that it is new, it exceeds the framework of mere professional skill and it is susceptible of industrial application.

Under Art. 4 of the Implementing Regulations to the Law No.350/2007, a utility model may protect products, such as devices, installations, equipments, machine-tools, apparatuses or

subassemblies thereof, electric, pneumatic or hydraulic circuits, physical mixtures which can be applied for solving a technical problem.

For filing a utility model, the standard form - Cerere de model de utilitate (Application for utility model), which can be found on the OSIM website, must be completed and filed with OSIM in three copies.

https://osim.ro/formulare-inventii

Along with the mentioned form, the applicant shall also file a documentation in three copies, containing a description of the utility model, one or more claims (as the case may be), drawings (if necessary for a good understanding of the technical solution) and an abstract, in three copies, as well. The three copies of the form and a complete set of documentation will be signed by the applicant (if he is a natural person), or signed by the legal representative and stamped, when the applicant is a legal person. This set of documentation will be the original copy.

The form will be signed in the dedicated fields, and the original copy of the documentation will be signed (and stamped, if the applicant is a legal entity) in the lower right corner.

Also, the applicant shall tick, on the form, which law entitles him to file the application for a utility model, i.e. Law no. 350/2007 on utility models, as republished in 2014, Law no. 83/2014 on employees' inventions or a research contract. Depending on the version on which the registration is requested, the document (or the contract, as the case may be) stating that the applicant is entitled to file the application for registration of the utility model will have to be filed.[1]

[1] https://osim.ro/en/basic-information-patents/utility-models/ghid-inregistrare-model-de-utilitate

1.2.4. Industrial designs

1) Subject matter of protection

Design right is an exclusive right protecting the appearance of a product resulting from features such as lines, contours, colours, shape, texture and/or materials of the product itself and/or its ornamentation.
A product is understood as an industrial or handicraft item, including parts intended to be assembled into a complex product packaging, get-up, graphic symbols and typographic typefaces.

Design right may protect the appearance of products such as, such as mobile phones, glasses, lamps, sport equipment, cars, jewellery, textile designs. Industrial design law protects solely the features of appearance of the product. Technical features are excluded from protection; however, such feature may be protected under patent law.

In the EU, designs rights are harmonized by directive, therefore the protection of designs under national laws of EU Member States is similar. Moreover, unitary protection of designs in the EU (EU design) has been established under the the European Union design regulation (formerly: Community design regulation).

Usually, under national laws, protection is granted upon filing an application. The same is required by the EU design Regulation. However, EU design right system provides protection

for unregistered EU designs as well. Such protection arises automatically, but comparing to the registered design right, it lasts significantly shorter that and its execution is more burdensome.

Designs can be protected if they are new and have individual character. The notion of novelty is understood differently from the novelty required to obtain a patent. The individual character requirement also differs from the originality which is essential for copyright.

Novelty

A design is novel if no identical design has been made available to the public before the date of filing of the application for registration of the design, or of priority date, if claimed. In the case of an unregistered EU design, the date relevant for assessment of novelty requirement is the date on which the design (for which protection is claimed) has first been made available to the public. Therefore, while examining the novelty requirement, we must refer to the prior art.

Designs are deemed to be identical if their features differ only in immaterial details.

Individual character

To establish whether a design has an individual character, an informed user model is applied. An informed user is a legal fiction of a person who uses the product protected under design right, who is observant and well-informed in a given sector. An informed user differs in the case of electric drills, professional paintbrushes, or mobile phones. One design may be used by different categories of users. For example, in a case of a toy gadget the informed user may be either a child that plays such a toy or a marketing manager in a company that makes goods which are promoted by giving away such gadgets.

The individual character is assessed from the perspective of informed user. If the overall impression produced by the design on the informed user differs from the overall impression produced on such a user by any design which has been already made available to the public (exists in the prior art), the design has individual character.

2). Scope of protection

Design protection covers the appearance of a product. The rightholder may prevent other parties from using an identical or similar design commercially. In particular, the rightholder has the exclusive right to:

- make, offer, place on the market, or use a product in which the design is incorporated or to which the design is applied;

- import or export a product incorporating/applying the design;
- stock a product incorporating/applying the design for commercial purposes (referred in points above);
- create, download, copy, and share or distribute to others any medium or software that records the design for the purpose of enabling a product incorporating/applying the design to be made:

An unregistered Community design protects only against deliberate copying. This means that a third party may use an identical design if they created it independently.

3). Duration of protection

In the EU, a registered design is protected for a maximum of 25 years from the date of filing of the application for registration. However, the rights holder must renew the registration every five years.
An unregistered EU design right lasts for three years from the date of public disclosure within the EU and cannot be renewed.

4). Right holder

The right to a registered design is generally vested in the designer. However, under national laws, this right may be vested in another entity.

5). How to obtain a design protection?

Usually, under national laws, protection is granted upon registration. To register a design, an application must be filed with the relevant office. protection is granted on the condition that all the requirements are met.

International application

The application can be made on an international level within the Hauge System, administered by WIPO. By filing single application, the protection may be obtained in selected countries (up to all the countries) that participate in the Hauge System (currently 91 countries). As a result of the procedure a bundle of national registrations may be obtained.

The application may be filled in directly with International Bureau of WIPO or with the relevant national office. The application is examined solely with respect to the formal requirements; WIPO does not conduct substantive examination of the application. Once the application passes the formal examination, it is published in the International Designs Bulletin. In the national phase, the selected national or regional offices can assess the application concerning substantive criteria (novelty, individual character) if it is required under relevant laws.

National or regional offices may refuse the application, if it does not meet criteria, other than formal ones, laid down in the applicable law. A refusal of protection must be notified to the International Bureau within six months from the date of publication of the international registration (or 12 months under specified conditions).

International registration is valid for an initial period of five years, and it can be renewed for a period of five years in each designated country. The total term of protection may vary between the designated countries and depends on the applicable law.

EU registered design

An applicant has to file an application to register a EU design with the European Intellectual Property Office (EUIPO) or to a national industrial property office.

An application for a registered Community design contains:

1) a request for registration;
2) information identifying the applicant;
3) a representation of the design suitable for reproduction (or a specimen, if relevant conditions are met);
4) an indication of the products in which the design is intended to be incorporated or to which it is intended to be applied.

Non-obligatory elements of the application:

1) a description explaining the representation (or the specimen);
2) a request for deferment of publication of the registration (the publication may be postponed for a period of 30 months from the date of filing, or priority date if claimed);
3) information identifying the representative if the applicant has appointed one;
4) the classification of the products in which the design is intended to be incorporated or to which it is intended to be applied according to class;

5) the citation of the designer or of the team of designers or a statement under the applicant's responsibility that the designer or the team of designers has waived the right to be cited.

EUIPO conducts mainly a formal examination of the application, however, if EUIPO, in carrying out the examination, notices that the application concerns a creation that is not a design (does not correspond to its legal definition) or the design is contrary to public policy or accepted principles of morality, it shall refuse the application. The decision may be appealed. If all requirements for the application are met, EUIPO grants the EU design to the applicant.

The application is published in EUIPO Design Bulletin. The applicant may request that publication be deferred.

The registered EU design entitles, on the exclusive basis, to use, make, offer, put on the market, import, export or stock products incorporating the protected design, and to prevent other entities from such actions concerning products incorporating the protected design that do not produce a different overall impression.

The registered EU design can be valid a maximum of 25 years from the filing date. It is initially valid for 5 years and it can be renewed for 5-year periods.

Unregistered EU design

Unregistered EU design is a right with unitary effect across the EU that arises automatically upon disclosure of the design to the public within the EU territory. The scope of the protection of the unregistered EU right is limited to the deliberate copying of the design. Moreover, if the protection is claimed (usually in the infringement proceedings), the disclosure and the date thereof must be proven, along with the intentional copying by the alleged infringer.

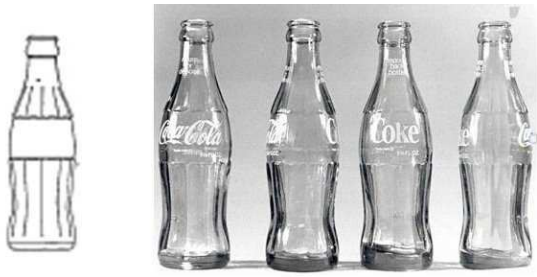
It is possible to apply for a registered design that has already been disclosed to the public if the application is made within12 months from the disclosure. Therefore, an unregistered EU design and Registered Community design may overlap. The term of protection is limited to 3 years from the disclosure.

1.2.5. Trade mark

1). Subject matter of protection

A trade mark may be grated for any sign, in particular words, designs, letters, numerals, colours, the shape of goods or their packaging, and sounds, provided that:

1) they are distinctive, meaning that are capable to distinguish the goods or services of one undertaking from those of other undertakings; and
2) can be represented on the respective register. The representation must enable the clear and precise determination of the subject matter of the protection.



Trade marks may be three-dimensional (e.g., the packaging of the goods, the shape of the goods like Toblerone chocolate), motion marks, as well as holograms, or colours per se (e.g., violet for Milka), as long as they have a distinctive character.

Distinctiveness

Distinctiveness is a corner stone of trademark protection system. A trade mark provides information on the commercial source of a given goods or services. The basic function of a trade mark is to distinguish products or services provided by one commercial entity from those provided by other entities.

A sign lacking inherent distinctiveness may acquire such character through use, for example red soles of Louboutin' shoes.

The exclusions from trade mark protection are usually listed in the applicable law. Generally, protection cannot be granted for marks which are devoid of distinctive character; marks that are descriptive; marks contrary to public policy or accepted principles of morality; marks that consists solely of the shape, or another characteristic of the good, which results from the nature of the goods, is necessary to achieve a technical result, or gives substantial value to the good. In the EU law, such conditions are called absolute grounds of refusal and are examined by ex officio by the relevant office.

Relative grounds of refusal refer to existing prior rights and are usually examined upon a request of an entity that has an interest in blocking the protection of a given trade mark .

Special types of trade marks:

- Collective trade marks – used to distinguish goods or services that origin from members of a defined association;
- Certification marks - are used to distinguish goods or services that are certified as complying with determined standards (e.g. Woolmark sign).

2). Scope of protection

Territorial Scope – trade mark protection extends to the boundaries of the country or region for which the trade mark is registered.
The protection granted under a registered trade mark applies to the class of goods or services specified by the applicant. The designated class of goods or services should always correspond to those commercialized by the rights holder (or their licensors). The list of classes of goods or services is established at the international level by the Nice International Agreement on the International Classification of Goods and Services, which is administered by WIPO.

The proprietor of a registered trade mark has the exclusive right to use the trade mark in the course of trade in relation to goods and services. The right holder can prevent other entities from using, in their course of trade:

- a sign that is identical to the trade mark and is used in relation to identical goods and services as those for which the trademark has been registered;
- an identical or similar sign used in relation to identical or similar goods, if there is a likelihood of public confusion, including the likelihood of association between the sign and the trade mark.
- a sign identical or similar to the trade mark, regardless of the goods or services for which it is used, if the trade mark has a reputation in the Member State and the use of the sign takes unfair advantage of or is detrimental to the trade mark.

3). Duration of protection

In the EU, trade marks are registered for a period of 10 years from the date of filing of the application. The registration may be renewed for successive 10-year periods without a general time limit.

4). Right holder

At the EU level, there is no legislation regarding the vesting of the right to register a trade mark, and such a right does not automatically arise in favor of the creator of the trade mark. However, Member States may provide, in their national legislation, a right to a non-registered trade mark or another sign used in the course of trade.

Moreover, if provided by national law, the existence of a non-registered trade mark or another sign may prevent the registration of a subsequent trade mark.

5). How to obtain a trademark protection?

Trade mark law, as well as design law, is harmonised across the EU countries through adopting relevant directives. At the same time, unitary protection of trademark s is offered under European Union trade mark regulation.

National registration

Under national regimes registration of a trade mark is made after filing an application with the respective national office. The office examines the application in respect to both, formal requirements and absolute grounds of refusal.

International registration

An international application may be obtained under the Madrid System administered by WIPO. Within this system a single international trade mark application is filed in order to apply for protection in selected countries simultaneously (Currently 131 countries).

In order to file an international application an applicant must first apply for trade mark registration (so-called “basic mark”) with the national office (“office of origin”) under the respective national regime. Subsequently, an international application may be filled in through the office of origin. After verifying whether the international application corresponds the basic mark, the office of origin forwards the application to WIPO. WIPO examines whether it complies with formal requirements. If the application meets all formal conditions, it is published the WIPO Gazette of International Marks and forwarded to the countries designated by the applicant.

The IP office of each selected country performs substantive examination of the mark. The decision on granting a trade mark registration or refusal must be made within 12 months from the notification of the relevant IP office about the designation (18 months under defined conditions).

The protection of the trade mark filed under the Madrid System lasts for an initial period of 10 years and may be extended indefinitely for further periods according to the applicable law.

European Union Trade Mark

The registration of a trade mark can be carried out at the EU level, and as a result of this procedure, the right holder receives unitary protection across the entire territory of all Member States. The application is filed with the European Union Intellectual Property Office (EUIPO) in the official language of any Member State, along with one of the following: English, French, Spanish, German, or Italian.

The application must contain the following :

- a request for the registration of a EU trade mark,
- information identifying the applicant,
- a list of the goods or services in respect of which the registration is requested,
- a representation of the trade mark.

1.2.6 Protection of Databases

The protection of databases under *sui generis* rights and copyright is harmonized in the EU by Directive 96/9/EC on the Legal Protection of Databases. This means that each EU Member State is obliged to adopt laws in compliance with the standards laid down in the directive.

In EU databases may be protected by both:

- copyright – if a database is an original work;
- *sui generis* right – if a substantial investment has been made in the obtaining, verification, or presentation of its contents.

While copyright protection of databases is recognized under international treaties, the sui generis right to databases is specific to EU countries.

- **Sui generis right**

1). Subject matter of protection

The protection applies to the arrangement of data where a substantial investment has been made, either qualitatively or quantitatively, in its obtaining, verification, or presentation. A substantial investment may involve financial resources, organizational efforts, labor, time and effort. The *sui generis* right does not protect individual data itself, but the entire database or a substantial part of it.

2). Scope of protection

The *sui generis* right grants the database maker the exclusive right to prevent others from extracting, re-using the whole or of a substantial part of the contents of the database.

3). Duration of protection

The *sui generis* right arises from the date on which the creation of the database was completed and lasts for 15 years, calculated from January 1st of the year following either:

- the completion of the database;

- the date when the database was first made available to the public (in case of the databases made available to the public before expiry of the term referred above).

The term restarts from the last substantial modification of a database. Introducing such changes results in a new database protected under the sui generis right. These modifications are evaluated qualitatively and/or quantitatively and may include the accumulation of successive additions, deletions, or alterations.

4). Right holder

The maker of a database is the person or entity that has made a substantial investment in the obtaining, verification, or presentation of its contents. The database maker takes the initiative and assumes the risk of investing, therefore do not qualify as database makers under this definition. In EU the rules applicable to databases created by employees are left to the discretion of the Member States.

• Copyright in databases

1). Subject matter of protection

Copyright protects databases as such when the selection or arrangement of their contents constitutes the author's own intellectual creation. Member States cannot apply any additional criteria to determine the eligibility of a database for copyright protection.

Copyright protection does not extend to the content of a database, which may separately be subject to independent IPR protection (e.g., a database of poems). Moreover, as explained in the chapter regarding works, copyright protects solely the form of expression and not the ideas or concepts underlying the work (in this case, a database).

2). Scope of protection

The author of a database, to the extent that the expression of the database is protected under copyright, has the exclusive right to:

- reproduction;
- distribution to the public;
- communication, display, or performance to the public;

– translation, adaptation, arrangement, or any other alteration, as well as the reproduction, distribution, and communication of the results thereof.

3). Duration of protection

The term of protection is governed by the national laws of each country. In the EU, economic rights last for the lifetime of the author and for 70 years after their death. In many countries, protection lasts up to 50 years after the author's death, which is the minimum term of protection established by international treaties such as the Berne Convention and the TRIPS Agreement.

4). Right holeder

Generally, copyright in a database belongs to its author, a natural person who created the database. The rules on vesting economic rights in databases protected under copyright that have been created in the course of employment, commission, or other contractual arrangements depend on national law.

1.2.7 Plant Variety Protection

Subject matter of protection

A plant variety is a defined group of plants, selected from within a species, with a common set of characteristics. A plant variety right is an exclusive right granted to the breeder of a plant variety that fulfills the conditions set out by the applicable law. These conditions usually include distinctness, uniformity, stability, and novelty.
Distinctness – The plant variety must be clearly distinguishable from all known varieties.
Uniformity – The variety must exhibit sufficient uniformity in its key characteristics used to define its distinctness.
Stability – The key characteristics of the plant variety must remain unchanged after repeated propagation.
Novelty – The variety must not have been sold or otherwise disposed of to others before filing an application. However, if the plant variety has been sold or otherwise disposed of, the novelty requirement may still be met if the applicable law allows exceptions under specific conditions.

Scope of protection

An exclusive right to a plant variety grants the rights holder the sole entitlement, in respect of variety constituents or harvested material of the protected variety, to produce or reproduce (multiply), sell, market, export, import, or stock the variety for these purposes.

Duration of protection

Under the International Convention for the Protection of New Varieties of Plants, exclusive rights to a plant variety are granted for a minimum of 20 years, and 25 years for trees and vines. National laws typically extend protection to 25 years for most varieties and 30 years for trees and vines. Generally, a maintenance fee must be paid; otherwise, the right will lapse.

Right holder

The breeder is entitled to register a new plant variety. A breeder is the person who bred, discovered, and developed the variety, or their successor in title. Typically, national laws stipulate that the breeder may also be the employer or commissioner of the person who bred, discovered, or developed the plant variety.

How to obtain a protection

National registration

To obtain protection at the national level, an application must be filed with the relevant national authority. During the examination process, the authority may grow the variety or conduct other necessary tests.

To obtain international protection, the breeder must file individual applications with national authorities. However, the International Union for the Protection of New Varieties of Plants (UPOV) has developed an online tool that helps applicants apply for breeders' rights with all participating offices.

Community (CPVO)

The Regulation on Community Plant Variety Rights allows for the protection of plant varieties through a Community right, which is uniform and valid in all EU Member States. To obtain

such protection, an application must be submitted directly to the Community Plant Variety Office (CPVO) or through one of its sub-offices or national agencies.

1.2.8 Trade secret

Trade secrets are information of commercial value that derivies from the fact of keeping the information confidential. It usually refers to trade - related technical, technological, organizational, busiess information that is not generally known within the relevant professional circles. Preserving the secrecy of the information provides competitive advantage to its holder.

The most famous example of a trade secret is the Coca-Cola recipe, which has been kept confidential since 1886.

Trade secrets are usually protected under national laws combating unfair competition. At the EU level, the protection of trade secrets is harmonized to some extent by the Directive on *the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure* (Directive (EU) 2016/943). EU Member States must adopt legal measures to implement the directive. They may also introduce more far-reaching protection against the unlawful acquisition, use, or disclosure of trade secrets than that set out in the directive, as long as such protection complies with established standards, for example concerning exceptions or the definition of lawful acquisition of a trade secret.

The directive defines the trade secret as information that meets all the criteria:

- It is secret in the sense that it is, as a whole or in its specific arrangement, not generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
- It has commercial value because it is secret;
- It has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

According to the definition, it is required that, for information to qualify as a trade secret, it must be subject to reasonable measures by the person in control of the information to maintain its confidentiality. These steps may include implementing legal measures (such as

non-disclosure agreements), organizational controls (like limiting access on a need-to-know basis), and technical safeguards (for example, secure data storage or restricted IT systems).

National laws protect trade secrets only in a limited way, specifically against certain unfair competition practices. Such protection does not confer an exclusive right. This means that, unlike patents or registered designs, information constituting a trade secret may be legally used or exploited by others if they independently develop it. Accordingly, if another company generates or lawfully acquires the same information, it may use it commercially or even disclose it publicly, provided it acts in accordance with honest commercial practices.

Trade secrets may complement an intellectual property rights portfolio. For example, an entity holding several patents and registered utility models can strengthen its market position by keeping additional information (e.g., know-how) confidential, even if this information does not qualify for IPR protection itself. On the other hand, in some cases trade secrets may serve as an alternative form of protection for research results that could otherwise be protected under IPR. For instance, an entity entitled to obtain a patent may choose to keep the invention confidential, thereby avoiding public disclosure in the patent register. This alternative has both advantages and disadvantages. While trade secret protection can be indefinite in time, it does not confer exclusivity. This means that if another entity independently develops the same invention, it may use it commercially, patent it, or disclose it to the public.

1.3 Basic principles of IP management: legal acts in force globally, and in the specific countries

The IP management indicates the strategic approach for protecting and maximizing the value of intellectual assets. IP management should be based on a set of strategic procedures for IP handling, during all the stages of its life, from its inception until the expiry of its protection (if such occurs).

IP management procedures should be tailored to the type of the entity (public university or SME, large enterprise), its size and main goals (mainly commercial approach or rather implementing a broader mission, like in case of HEI). However, regardless of the type of the entity, a department (or person) responsible for the overall supervision of the process should be determined.

The main aspects of IP management procedures are:

- identification of potential IP;
- assessment of its commercial exploitation potential;
- IP protection - identification of the available forms of protection and decisions in this regard;
- IP due diligence;
- valuation of IP;
- compliance & monitoring of IP (including identification of infringements) and the procedures themselves;
- enforcement of rights.

Effective management of IP can enhance its value by, among other things, using legal frameworks to protect and exploit IP. Moreover, adopting procedures on identification of IP, accompanied by relevant trainings and raising awareness among employees, may result in expansion of the IP portfolio.

IP strategy is important not only from the perspective of research institutions, but also for businesses of all sizes. Adopting effective procedures for IP handling, covering all phases of IP existence, can strengthen a business's market position, generate additional revenue streams, avoid legal risks, and increase business value of the entity.

1.4.1 Key elements of IP management

1) Identification of IP

A small enterprise may entrust IP identification to a specialist who periodically audits the results obtained within the enterprise, whereas large entities usually have to rely on the employees' awareness. The latter should be supported by relevant training on recognizing intellectual results that should be notified to the relevant department.

Such results should be appropriately described and recorded. Confidentiality rules should be adopted regarding these intellectual results to keep all the IP protection possibilities open (including patenting or keeping it as a trade secret). It is important that the employees and collaborators are aware of those confidentiality rules.

Identification of IP must also concern IP acquired from external sources. Agreements governing relationships with external providers should contain necessary intellectual property

transfer clauses. It should be emphasized that rights to results obtained under commission or contract order are usually governed differently than rights to results obtained under an employee contract. Some national laws provide for the automatic assignment of rights to the employer, whereas in B2B relationships such provisions do not apply. Therefore, particular attention should be paid to appropriate management of such contracts. The acquisition of IPR under an employment contract or commission is described in detail in Chapter 3.

2) Collaboration agreements

R&D is often conducted in collaboration with other entities. Such collaborations should begin with a specific agreement governing intellectual property rights. This agreement should clearly define the tasks assigned to each party. In this context, the results of the collaboration refer to all outputs generated by performing these tasks.

All collaborators should outline any background necessary to conduct the R&D. Background typically refers to knowledge or data (including IPR) held by one of the collaborators prior to the start of the collaboration and necessary for implementing the tasks set out within the collaboration framework.

The collaboration agreement should specify the rules regarding entitlement to the results and establish access rights to both the background and the results. If Party A is granted access rights to results or background owned by Party B, it means that Party A, under certain conditions, may request a non-exclusive license or other legal basis to use Party B's results or background for a defined purpose.

As a result of R&D collaboration, the parties often become joint owners of the results and respective IPR. In such cases, joint owners must enter into a joint ownership agreement that specifies each party's share in the IPR and the rules for exercising these rights. Details of IPR joint ownership are outlined below.

3) Assessment of the commercial exploitation potential of IP

A detailed description of the assessment of the market potential of IP is presented in Chapter 2 of the Curriculum. An initial assessment of such potential should be performed as part of the IP protection strategy. The company or university should define key factors of the commercialization landscape, such as: target market, including the identification of direct recipients and end users; analysis of the competition; production costs, including relevant concessions or legal requirements.

The overall view of the commercialization strategy and the awareness of predicted costs will impact the choice of IPR protection paths. IP protection should be tailored to the needs of the commercialization strategy, for example, by selecting the relevant territory of protection or adapting the preferred form of protection, such as keeping an invention as a trade secret instead of patenting it.

If, as a result of the commercial potential assessment, the IP is determined to have strong commercialization potential, investment in extending IPR protection should be considered. Conversely, if the IP has low commercialization potential, the legal protection strategy should be adjusted, and its costs minimized.

4) Protection

As a first step, an assessment of available protection paths should be made by a specialist in the field of IPR, such as a patent attorney or legal advisor. After determining possible ways of IP legal protection, the option that aligns with the entity's strategy can be chosen. Different models of IP protection may be appropriate, taking into account factors such as the potential value of the IP, financial resources allocated for protection, the model of its commercialization (e.g., implementation by the company itself, transfer of rights, licensing), and the temporal and territorial scope of the protection.

To preserve a wide range of protection paths, intellectual results should be kept confidential until competent body decides otherwise. In this manner, intellectual property rights granted based on novelty conditions may still be obtained (e.g. registration of utility model or granting of a patent). Moreover, the proprietor may decide that the most suitable form of protection for the results is to keep them confidential (e.g. as a trade secret). Therefore, adopting confidentiality rules, both internally within the entity and externally in relationships with third parties, is crucial.

5) Due diligence

One key aspect of IP management is IPR due diligence. This process is typically conducted before entering into agreements such as IPR transfers, licensing arrangements, mergers and acquisitions, or joint ventures. IPR due diligence focuses on verifying all legal aspects related to intellectual property rights in the context of the planned agreement should be conducted by each party involved in the agreement. For example, it should be done by both, the licensor and the licensee before entering the license agreement. From the perspective of the licensor, IPR due diligence allows them to make representations and guarantees regarding the licensed IPR. On the other hand, as a result of the IP due diligence conducted by the licensee, they will

have greater legal certainty in using the licensed IPR without infringing on third-party rights. During the due diligence process, IPR ownership, scope of protection, and regulatory compliance are examined, IP-related risks are identified, and IP assets are evaluated. The process results in a comprehensive report that details all relevant aspects and highlights any associated risks in relation to the planned agreement.

Due diligence should be conducted with regard to each identified IP, and relevant records should be kept for each R&D result. In this manner, it can be easily evidenced that each IPR protecting a given result is vested in the company or university. Therefore, the creators of a particular IP should be identified, and the contracts governing their work (e.g., employment contracts or commissions) should be properly recorded and include all necessary IPR clauses. The methods of acquiring ownership of IPR for R&D results are detailed in Chapter 3.2.

6) Joint ownership

Joint IPR ownership can, in simple terms, be compared to joint ownership of real estate. Joint owners are entitled to shares in a common asset. However, with intangible assets, the situation is far more complex. National laws govern joint ownership to some extent concerning specific intellectual property rights (such as patents, utility models, designs, trademarks, and copyrights). General rules on the management of jointly owned rights and the entitlements of joint owners are provided in relevant national laws. Typically, joint owners may modify some of these general rules through a joint ownership agreement. Such an agreement should cover:

- methods for protecting jointly owned IP;
- allocation of costs related to legal protection;
- procedures in case of infringement by a third party;
- division of benefits from the use of the IPR;
- the IPR exploitation rules, including rules for granting licenses to third parties;
- choice of governing law and conflict resolution mechanisms.

The content of such an agreement will depend on the nature of the rights protecting specific categories of intellectual property. This means that the joint ownership agreement should include provisions tailored to the type of intangible asset (e.g., new plant variety, confidential information, computer software, invention).

7) **Valuation**

IP valuation is the process of identifying the economic value of intangible assets. It is essential for technology transfer purposes, mergers and acquisitions, strategic business decisions (e.g. allocating resources to high-value IP), tax and accounting purposes, and litigation (to calculate potential damages).

The value of IP depends on its nature, methods of protection, scope of protection (including geographical and temporal scope), and potential competition (e.g., substitutes or technologies that fulfil the same market need).

The potential value of intangible assets determines the decision on appropriate protection measures; however, these aspects are mutually dependent. The broader the scope of protection is applied (in terms of quality or quantity), the value of the IP increases. For example, if an invention is patented on the territory of several countries, its value significantly increases compared to the same invention protected in only one country. Similarly, if the same innovation is protected under a patent, it will be more valuable than if it is protected as utility model.

The value of IP should be established by an expert specializing in such valuations. The commonly accepted methods of IP evaluation are as follows:

- cost-based approach - the method refers to the costs incurred in developing the IP. Relevant costs may be historical (such as actual R&D expenses) or replacement costs (the estimated cost of recreating the IP). This method is simple and straight forward, however, it does not consider the potential future value of the IP.
- market-based approach – the method is based on analyzing historical data from licensing or IPR transfer agreements involving similar assets to the IP being evaluated.
- income-based approach – the method values IP based on the expected future income generated by the IP, discounted to its present value. Income-based approach includes:
    - royalty relief method,
    - discounted cash flow (DCF).

All of them are presented in the Chapter V of this Curriculum.

8) Exploitation

Once intellectual property (IP) is identified and protected, it can be exploited by the entitled entity. The exploitation of IP refers to utilizing these assets to generate revenue. Such exploitation is only possible when the IP is legally protected (e.g., through exclusive rights

granted by intellectual property laws or through confidentiality agreements). Possible ways of IP exploitation include:

- Business implementation – directly using the IP in the business. For example, the IP may be incorporated into the offered product, used to provide services, or applied in the production of goods.
- Licensing (including franchising and merchandising) – allowing another entity to use IPR in exchange for royalties.
- Using IPR as a tool for fundraising – IPR can be used as an in-kind contribution to a company and to attract investors. Business angels and venture capital funds often invest in companies with a strong IPR portfolio.
- Transferring ownership of IPR – selling or assigning IP rights to another entity.
- Pledging IPR as collateral – IPR can be used as collateral for securing a bank loan.
- Developing IP in further projects or partnerships – expanding and leveraging IP in new ventures or collaborative agreements.

9) Compliance and Monitoring

Compliance & monitoring (C&M) are important elements of the IP management. An entity should continuously monitor the exploitation and protection of its IP over the time. All activities related to IP have to comply with legal regulations, internal procedures, contractual obligations. In that manner, an entity can avoid infringement of third-party rights and mitigate risk associated to the use of IP. At the same time, it can effectively monitor the protection and utilization of its own IPR. The first step in ensuring compliance is having a clear understanding of relevant obligations.

Compliance & monitoring should be carried out in relation to:

<u>Internal procedures</u>

IP- related procedures are aimed to foster the identification, assignment, protection and enforcement of IPR. Therefore, it is essential for any entity to ensure the effectiveness of such procedures. Employees and collaborators should be properly instructed and trained on the necessary steps to protect IPR related to research and development activity. This includes notifying the employer about the creation of any IP, maintaining the confidentiality of the results, and securing appropriate legal protection. Compliance, however, begins at the level of employment contracts or B2B partnerships. A business entity or a research institution should always ensure the assignment of IP rights to the results generated under any such contracts.

Contractual compliance

Contractual obligations related to specific IP must be clearly defined and adhered to. Terms, royalties, scope of rights, operating restrictions, and non-disclosure obligations governed by agreements should be followed diligently. To that end, all employees involved in IP-related activities must be made aware of these obligations and instructed accordingly. This applies to any agreement, collaboration, or partnership entered into by the enterprise or university.

These obligations apply to both, IP crucial for the business—such as irreplaceable licensed trademarks—as well as intellectual goods used in the course of business that can be replaced, such as software for order and invoicing management or highly specialized software used for R&D purposes.

Grant agreements, particularly those involving public funding, present a specific case. It is vital for enterprises or research institutions to comply with all obligations set forth by the granting authority concerning the results of the project, such as IP protection, assignment of rights, exploitation, or any required forms of dissemination.

Legal regulations

Each entity must ensure compliance with legal regulations at both the national and European levels. The obligations related to IPR may include, for example, the registration and maintenance of industrial property rights or the use of IP within the statutory exceptions or limitations of the IPR monopoly. It is also essential to correctly identify the applicable law in specific cases.

A separate legal area concerning IP that must be adhered to is competition law and consumer protection regulations.

Compliance may also extend to industry-specific regulations related to IP, particularly in sectors such as energy, pharmaceuticals, and waste management.

Monitoring of Infringements

Effective monitoring of IPR infringements is essential for safeguarding the value and exclusivity of protected assets. The IPR holder should proactively monitor the market to ensure early detection of unauthorized use and take timely enforcement actions. Monitoring may include tracking competitors, reviewing relevant publications, and searching databases (e.g., trademark registries).

10) Enforcement

IPR Enforcement

IPR enforcement is a legal action aimed at stopping IPR infringement and remedying the damages caused by it. Enforcement of IPR is an essential tool in the effective protection of IP.

If, in the course of monitoring IPR, an infringement of the company's or university's IPR is identified, the relevant actions must be undertaken to safeguard the rights holder's interests. As a first step, the infringement should be assessed in the context of its severity, impact (for example, on revenue, reputation), and possible legal actions. All of these factors shall determine the next steps.

IPR enforcement may include actions such as:

- Filing a case before civil or administrative authorities – it should be underlined that in IPR infringement cases, applications for provisional measures play a crucial role. Such measures are temporary actions issued by a competent authority before the final decision in the case. Provisional measures are aimed at preventing further infringements or preserving evidence relevant in the case.
- Initiating criminal proceedings, if applicable (e.g., counterfeiting, piracy, plagiarism).
- Requesting customs authorities to take relevant action to intercept infringing goods at the border and to prevent such goods from entering circulation (so-called border measures).
- Negotiations – Sometimes, it is more profitable to resolve IPR infringement amicably.

Contractual Enforcement

In the event of a contract breach (e.g., a license agreement), the contractual obligations should also be enforced. When dealing with contracts, the value of the business relationship should be assessed, and, in general, breaches should first be handled amicably.

As a first step in contractual enforcement, a justified notice should be issued to the breaching party, stating the breach and requesting relevant actions. Contracts usually contain clauses on dispute resolution, which may require negotiations as the initial step or even mandate that future disputes under the agreement be submitted to mediation procedures.

If a contractual party's actions are limited solely to a breach of contract, without violating any applicable laws, the other party may enforce the contract through civil proceedings.

11) Education and Training

One of the crucial elements of IP management is raising awareness among employees and other individuals engaged in R&D regarding internal procedures and rules on IP handling, especially confidentiality obligations. Appropriate IP handling and adherence to procedures can be ensured only by individuals who are adequately trained.

Awareness of IP procedures can be developed through staff training programs tailored to the needs of the given entity. This should include internal procedures, compliance with contractual obligations, and general education on IPR.

1.4 Dissemination of the Developed IP

1.4.1 General Remarks

Dissemination of research results refers to presenting them to the public. The audience may include a specific industrial sector, academia, scientists, or the general public. Dissemination of scientific achievements is one of the core activities of HEIs; however, it can also serve as a valuable tool for entrepreneurs. From the latter perspective, dissemination may help in finding business partners, building the company's market position, and communicating with consumers.

Dissemination channels should be tailored to the type of research results and the intended audience. These channels will differ depending on whether the goal is to reach professionals in the field, policymakers, or the general public.

Common dissemination channels include traditional ones such as scientific publications and presentations at scientific or industry conferences. When targeting a broader audience, popular science articles, social media, and platforms like YouTube may be effective.

Importantly, dissemination should be planned strategically and aligned with the IPR protection strategy. Communicating research results to stakeholders or the public should always be a deliberate decision. If the optimal way to protect certain results is to treat them as confidential know-how, such outputs should not be expressly disseminated, and the scope of information shared about them must be carefully considered. Any substantial information that constitutes know-how should be excluded from dissemination.

If the results can be protected under industrial property rights depending on their novelty, a relevant application should be filed before dissemination. However, in such cases, it is

generally recommended to share the results only after the application has been published in the relevant bulletin (e.g., a national patent office bulletin).

1.4.2 Higher Education Institutions - A specific case

From the perspective of Higher Education Institutions (HEIs), the dissemination of research results is essential for achieving real impact. Research outputs should be shared with entities and stakeholders who can effectively apply them - such as organizations operating within relevant industries, legislators, and research funders. Furthermore, these results should also be communicated to the general public.

While the dissemination of scientific achievements is part of the core mission of HEIs, it must be emphasized that such dissemination is subject to internal procedures and typically cannot be left to the sole discretion of the individual researchers involved.

At HEIs, research results must be disclosed and registered with a dedicated unit, usually a Technology Transfer Office, prior to any public presentation. This process ensures that potential legal protection strategies are properly assessed. If applicable and justified, an application for legal protection based on novelty (e.g., in the case of an invention or utility model) should be submitted before dissemination. Without such precautions, securing legal protection may become impossible once the results have been made public.

Additionally, HEI authorities may decide not to disseminate certain results and instead protect them as confidential know-how. If the results are not eligible for legal protection under exclusive rights, such confidentiality may be the only viable pathway to commercialization.

1.4.3 Steps for Effective Dissemination

1) First step: Plan your dissemination in line with the IPR protection strategy

Define the subject of dissemination and verify its legal protection status, including all necessary prerequisites that must be fulfilled before the results can be shared.

Note: Dissemination of research results generated within scientific collaborations may be subject to additional restrictions outlined in collaboration agreements. For example, it may require prior notification to project partners or obtaining their consent.

2) Clearly identify the objectives of the dissemination, as this will determine subsequent steps. The aim may include:

   - Communicating specific findings to the public,
   - Enabling public debate or awareness,
   - Facilitating follow-up research,
   - Showcasing innovation to consumers,
   - Seeking business partners or investors.

3) Define the audience

   Depending on the purpose, the target audience may vary (e.g. policymakers, industry professionals, researchers, general public). Identifying the right groups is key to meaningful communication.

4) Characterize the audience

   It is important to prepare a general profile of the targeted group to adjust the form and channels of the communication. Understanding the audience helps maximize the impact of the dissemination efforts.

5) Tailor your communication

   Once the purpose and the audience are defined, it becomes possible to tailor the message accordingly. The following factors should be considered:

   - What is the audience interested in?
   - What do they want to know about the research?
   - What will capture and retain their attention?
   - What is the best format and language for the message?

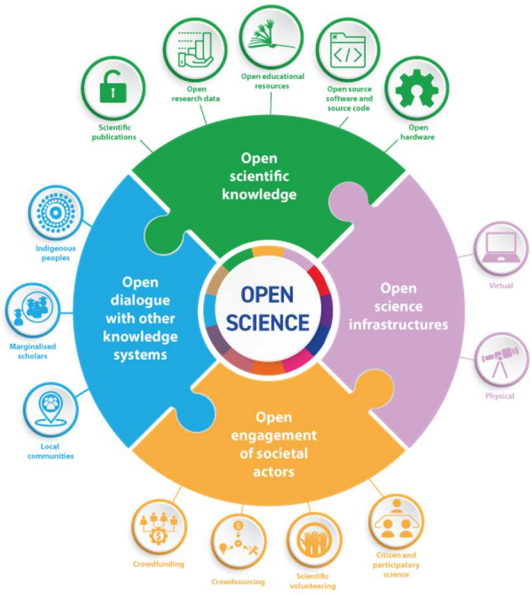
6) Choose the appropriate dissemination channels

   Select channels that best align with your audience and purpose—such as scientific journals, social media, public events, industry conferences, policy briefings, or educational platforms.

7) Plan the dissemination

   Assign responsible individuals or teams, allocate a budget, provide necessary tools, and define key milestones and timelines to monitor progress. The dissemination plan should be flexible and adapt to changing circumstances.

1.4.4 Open science



Open science (open research is a movement that promotes conducting research in a transparent, accessible, and collaborative manner. It emphasizes broad dissemination of research results and encourages their reuse by others.

The concept encompasses multiple dimensions, including open access to knowledge (e.g. open access publications, open data, open source software), shared research infrastructures, dialogue with other knowledge systems, and active engagement of societal actors.

Open access is an international movement aimed at providing free and unrestricted access to research and educational resources. It is one of the key pillars of open science. Open access refers to a mode of publishing copyrighted works in a way that allows readers to access them free of charge and without other barriers.

Moreover, such publications can often be reused, downloaded, and distributed under specified open licenses.

This mode of publication is frequently required as part of publicly funded research projects.

Part 2: Market Potential of R&D

2.1 State of the art

When planning a research and development (R&D) project, it is extremely important to review the current state of the art in the research area. Researchers have to check whether there are already existing solutions that could be an obstacle to the implementation of future R&D results. This will allow them to effectively secure future R&D results and plan an appropriate commercialization strategy.

The objectives of the state-of-the-art analysis are:

- Identify existing solutions in a given technology area;
- Determine the direction of research;
- Protect the inventor from repeating known and protected solutions;
- identify the latest trends.

According to the European Patent Convention (art.54), the state of the art includes everything made available to the public through written or oral descriptions, use, exhibition or any other form of disclosure before the date of filing of the European patent application or the priority date, if claimed.

In the marketplace, the state of the art is a somewhat broader concept. It refers to all currently manufactured devices, applied patented and unpatented methods, solutions, ongoing research and development, as well as publications in the field.

State of the art research, i.e. research into the patent environment of a particular technology or industry, is part of basic patent research. It involves a detailed analysis of existing solutions in a given field, known from patent literature, scientific publications, articles and practical applications. The aim is to determine the state of development of a particular technology and identify existing solutions.

In commercialization processes, the prior art search is also a tool for planning the development of a new product/technology, especially for projects whose success is based on an innovative solution.

The state of the art and freedom to operate analyses support the market development decision process. They help determine whether there are similar or identical solutions that have been filed for protection or for which exclusive rights have already been granted in the country and/or abroad. Such analyses minimize the risk of lawsuits by holders of existing exclusive rights and help avoiding the potential litigation costs and damages.

In preparing a patent application, a patent purity examination and a patentability examination are also carried out.

Patent purity examination aims to determine whether a product, technology or service infringes on the intellectual property rights of others. In other words, assesses whether you can freely market your product without the risk of being sued for patent infringement.

Patentability examination is a process that aims to assess whether an invention meets the legal requirements for patent protection, meaning it is novel and non-obvious.

The tools used for these searches include patent databases and search engines.

- Patent databases of the patent offices of individual countries:
  In Greece - https://www.obi.gr/obi/Default.aspx?tabid=125
  In Poland - The Patent Office of the Republic of Poland
  https://uprp.gov.pl/pl/wyszukiwarki
  In Romania - https://www.osim.ro/inventii-buletinul-oficial-de-proprietate-industriala
- **ESPACENET** database of the European Patent Office (EPO) - https://worldwide.espacenet.com/
- **PATENTSCOPE** database of the World Intellectual Property Organisation (WIPO) - https://www.wipo.int/patentscope/en/
- Commercial patent data search engines that aggregate data from the patent offices of individual countries, e.g. **ORBIT INTELLIGENCE, Dialog, PatBase, STN,** etc.

2.2 Innovativeness of the project results

Innovativeness involves preparing and initiating the production of new or improved materials, products, equipment, services, processes or methods intended for market use or practical application. Innovation is sometimes defined as a creative activity that begins with the perception of an opportunity, a need to be met or a problem to be solved. The process comes to an end when a decision is made to implement a specific idea, selected from many considered, and to proceed with its implementation. Without a concrete market application, we are not talking about innovation, just an idea. Innovation occurs when the result of this activity is brought to market.

Innovation in research and in economic and social life is a key factor in business development and improving the quality of life of citizens. It is one of the strategic objectives of the European Union.

Innovation is essential for the long-term success of an organisation. Examples include the development of new products or services introducing new business models or achieving a competitive advantage through innovative solutions, leading to growth and entrepreneurship and a sustainable market position.

The Oslo Manual 2018 defines innovation as:

"A new or improved product or process (or a combination thereof) that is significantly different from previous products or processes".

A distinction should be made between the degree of innovation, i.e.:

Radical innovations: Innovations that redefine markets and lead to the completely replace previously used solutions and technologies.

Incremental innovations: Iimprovements to existing products or processes.

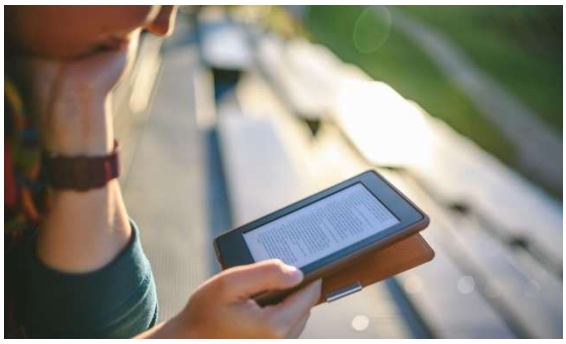
This means that not only new products or processes are considered innovations, but also those solutions that bring significant improvements. These improvements must provide new functionalities or features that are relevant to the end user and provide specific benefits.

Innovation can also be considered in terms of scale of impact, whether on an individual /enterprise, national or global scale.

There are five main categories of innovation:

1. Product innovation - any type of change that improves a product already manufactured by a company, or initiates the production of another innovative product;

Example: E-book reader - the introduction of the e-book reader has revolutionised the way books are read. Now one small device can hold several books.



2. Process (technological) innovation - a change in the methods used by a company to provide services or manufacture products.

Example: An example of process innovation could be the introduction of new holiday booking software in a travel agency, the use of barcodes to track the flow of goods, or the use of GPS tracking devices to manage a fleet of vehicles

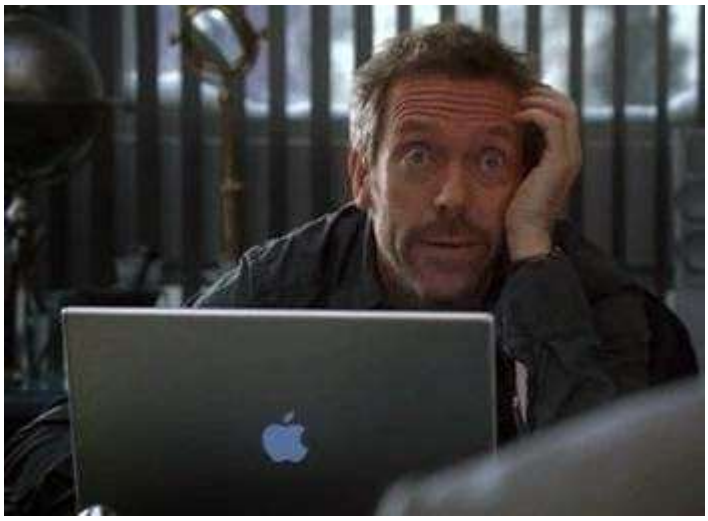
Another example would be the use of machinery to make butter.in the accompanying picture we can see butter production in the past and now.

3. Organisational innovation - is the introduction of a new method of organizing the way a company conducts its business;

Example: Reorganizing departments in a company to streamline a core process, creating new teams, implementing new management methods, the automation of information flows (using tablets to fill in documents in a production environment so that the area manager has real-time data).

4. **Marketing innovation** - involves the use of a new method of promotion that involves significant changes to a product's appearance, packaging, advertising or business model.

Example: Hiring celebrities (actors/singers) to promote new products or placing new products in films/series/television clips.



5. Social innovation - is an innovative activity whose primary and intended effect is to meet a real social need or address a real problem.

Example: shopping bag with wheelchair attachments.

Źródło: https://innoes.pl/innowacje/6

Innovation in each category can take different forms. It can also be understood differently depending on the field of knowledge to which it relates and the object of research and purpose it serves. The European Union's innovation-oriented economic policy has defined regional innovation strategies in individual member states. These are based on the identification of economic priorities in the field of R&D&I and the concentration of investments in areas that ensure an increase in the added value of the economy and its competitiveness in foreign markets.

An important role in such strategies is played by smart specialisations selected and developed by a given region. They should contribute to the transformation of the national economy through modernization, structural transformation, differentiation of products and services and the creation of innovative socio-economic solutions. They also support the transition to an economy that efficiently uses resources, including natural resources.

The main condition for the development of intelligent specialisations is to use the potential of each region by optimally matching the directions of scientific development and education to its social and economic specifics.

The list of Polish National Smart Specializations currently contains 12 items and includes:

KIS 1. HEALTHY SOCIETY
KIS 2. MODERN AGRICULTURE, FORESTRY AND NUTRITION

KIS 3. SUSTAINABLE (BIO)PRODUCTS, (BIO)PROCESSES AND ENVIRONMENT
KIS 4. SUSTAINABLE ENERGY
KIS 5. INTELLIGENT ZERO EMISSION BUILDINGS
KIS 6. CLEAN TRANSPORT
KIS 7. CIRCULAR ECONOMY
KIS 8. ADVANCED MATERIALS AND NANOTECHNOLOGY
KIS 9. ELECTRONICS AND PHOTONICS
KIS 10. INFORMATION, COMMUNICATION AND GEO-INFORMATION TECHNOLOGIES
KIS 11. AUTOMATION AND ROBOTICS
KIS 12. CREATIVE INDUSTRIES
KIS 13. MARINE TECHNOLOGIES

The new National Smart Specialization Strategy in Greece led to the identification of eight priority areas, which are the following:

1. AGRO-FOOD VALUE CHAIN
2. BIO-SCIENCES, HEALTH AND PHARMACEUTICALS
3. DIGITAL TECHNOLOGIES
4. SUSTAINABLE ENERGY
5. ENVIRONMENT AND CIRCULAR ECONOMY
6. TRANSPORT AND LOGISTICS
7. MATERIALS, CONSTRUCTIONS AND INDUSTRY
8. TOURISM, CULTURE AND CREATIVE INDUSTRIES

The main areas of specialization for Romania include:

1. BIOECONOMY
2. DIGITAL ECONOMY AND SPACE TECHNOLOGIES
3. ENERGY AND MOBILITY
4. ADVANCED MANUFACTURING
5. ADVANCED FUNCTIONAL MATERIALS
6. ENVIRONMENT AND ECO- TECHNOLOGIES
7. HEALTH - PREVENTION, DIAGNOSIS, AND ADVANCED TREATMENT[2]

The innovativeness of the outcome of a specific project lies in the fact that the developed product/technology should have unique features that are unknown or almost absent in the market. The innovative result of the project is expressed in the novelty of the features of the

[2] https://uefiscdi.gov.ro/resource-867892-SNCISIenglish-version.pdf%20

product we want to launch on the market. We should not forget that the novelty of the project results, in line with the expectations of the recipients, is one of the main factors determining the qualification of our product as a response to market demand, i.e. a necessary condition for successful commercialisation.

Research and research-implementation projects and business activities aimed at introducing innovative solutions to the market, in accordance with the directions set by the National Intelligent Specializations, receive financial support from the European Union within the framework of the European Funds for Modern Economy (In Poland: FENG; perspective 2021-2027) programme.

2.3 Competitive analysis

A competitive analysis is an essential step in evaluating the market potential of the outcomes of a research and implementation project. If the project's result is identical in terms of manufacturing costs, operating costs, features, durability, etc. to existing products or services, implementation will be very challenging or even impossible. Generally, a new product can only be successfully launched if it significantly differs from competing products in these aspects.

Competition is defined as the phenomenon where market participants pursue their interests by offering more favourable than others, such as better prices, quality, delivery terms and other features that influence the decision to do business (*Wikipedia*).

Colloquially, we refer to all companies operating within a particular industry and the services and products they offer as competitors.

Developing a new product or service necessitates an analysis of the competition it will face. The market does not operate in a vacuum; there is always some level of competition.

Competition manifests itself at various levels:

1. One of the fundamental criteria for comparison is **price.** The price range of products linked to the purchasing power of the customer segment that the product is intended to reach. If buyers cannot afford a particular product, they will substitute it with a more affordable alternative. Therefore, the pricing policy of competitors should be thoroughly analysed before launching a product monitored continuously while the product is on sale. Changes in competitors' prices can weaken our offer (if they

decrease) or strengthen our decrease position x (if the prices of the competition increase).

It is common for competing products from different suppliers to be available in the market at similar price levels. This is due to the need to maintain the quality expected by the customers, which is related to the production costs of a product with the desired characteristics. The lack of product differentiation leads to similar prices. Competition then takes place through branding. Division by product brand refers to companies that produce very similar products, differing mainly in name. It is a strategy focused on shelf competition, where different brands try to attract customer attention by offering similar products. Brands compete mainly by reducing production and distribution costs, resulting in different levels of profit.

2. The second basic criterion of competitiveness is **function**. Competing products can be identified by the function that they are designed for or the function they actually perform. Products or technologies should not be excluded from the competitive analysis due to different design or origins. Products with different physical features may successfully perform the same or similar functions and therefore constitute a competitive offering. In this case, they are substitutes or replacements.

3. Competition can also affect the market through its **geographical distribution**. Producers tend to have a strong position in regions where their production facilities and main distribution networks are located, as they have better access to consumers without incurring high storage and logistics costs. When planning to enter a particular market, therefore, geography, logistics bases, and transport availability must also be taken into account.

4. **The way competition is organised** also impacts consumer choice. Companies that are members of producer or supplier organisations have a greater market impact, by offering a wider range of products. It is difficult to compete with a single product when competitors offer a range of similar solutions. Individual suppliers are usually unable to compete with networks.

5. An important competitive factor is **the level of warranty and after-sales service**. Consumers are more likely to choose products from companies that offer extended warranties and the ease and speed with which the product can be repaired or returned. The proximity of the service centre to the customer is an important purchase criterion.

6. An increasingly important factor is **the environmental impact** of a product, its sustainability. This is a criterion often used in companies' marketing campaigns and

cannot be overlooked when analysing the competition. The circular economy is becoming an increasingly important fact here with its consequences as to product life cycle.

Competition in the market usually takes place at all these levels simultaneously. Buyers who cannot afford higher-end products will choose lower quality products or substitutes, deliberately foregoing certain features. The **quality/price ratio** becomes the main criterion for purchasing one product over another. Brand loyalty, ease of purchase and after-sales service are also important selection criteria. However, a relatively small number of customers choose products based on environmental characteristics.

When analysing the competition, all these factors must be considered to determine where we can compete effectively and where our position is too weak to enter and sustain a market presence with a new product.

2.4 Customer market analysis

When designing an innovation, it is crucial to identify the target audience as early as the concept development phase.

An analysis of the customer market helps us understand what is most important to the target group when choosing a particular service or product, and what influences their choice of a specific supplier or service provider. A potential customer should feel a significant need that is not being met by any solution on the market and have a strong desire to fulfil that need. The ideal innovation is 'tailor-made' for the customer's needs. The first step is to define whose needs our product can satisfy in the broadest sense, i.e. who has an unmet need. We then divide them into groups based on different purchase decision criteria, such as:

- Price
- Quality
- Appearance
- Availability
- Purpose
- Range of functions
- Safety of use
- Possible restrictions (physical, formal)
- Ease of use
- Product life cycle (single/multiple use)
- Warranty and repair conditions

- Ease of replacement
- Disposal conditions (payment for used product)

It's important to note that while customer groups may share common decision-making criteria, the weight of each criterion will vary among groups. When analysing buyers, we should understand not only their preferences, but also their numbers. The number of buyers willing to buy our product will determine the size of the market, i.e. ultimately the volume of sales.

Example: Customers may have a strong need for a solution with a long life cycle, but the requirement for higher quality materials increases the product's price. Some customers may not afford the higher-priced product and opt for a cheaper disposable version to meet their immediate need.

The product technologist must decide whether to design a reusable, higher-priced product or a disposable, lower-priced one based on customer market analysis.

A small number of buyers willing to pay more for better quality versus a large number of buyers needing an immediate, affordable solution will influence the decision. Conversely, if most buyers expect high quality and are willing to pay for it, the product has higher sales potential.

2.5 Defining the target segment

After analysing the market of potential buyers, we need to decide which group of buyers our product is intended for. If we define multiple groups, we must prioritize which group to target first. Even if the product has characteristics that allow it to be used by different groups of consumers, marketing efforts should focus on one segment initially.

This chosen segment is the group most likely to use it, i.e. those with the strongest motivation to buy. For this group, our product must be both attractive, i.e. meet a pressing need, and accessible, i.e. within the budget that this type of audience usually has. Correctly defining the target audience segment is crucial for commercializing the project results.If sales fail, it may be necessary to redesign the product for other audiences. Therefore, we should first look for the most determined consumer and define the target customer precisely.

Criteria for defining the target segment can be:

- gender

- age
- place of residence
- occupation
- social status
- income
- marital status (family or single)
- leisure activities (hobbies)
- typical habits of a certain group

The target segment should also be quantified using statistics, demographics, social reports, market reports, etc.

Example:

If market a cosmetic for the face exposed to urban smog, we might filter as follows:

- Gender: female (more sensitive skin group)
- Age: 40 - 55 years old (more likely to notice aging signs and be motivated to buy)
- Where they live: large cities (higher air pollution)
- Social status: working women (less time for personal care)
- Income: middle-income consumers using chain drugstores

While there will be a group of consumers outside the selected segment who will use the product, the main promotional campaigns should target the defined segment.

Determining the size of the group is important for forecasting sales and and pricing the product.

2.6 Market restrictions - admission to trading

Once we have defined our target segment, identified our competitors and determined the products we will be competing against, we need to identify the formal requirements necessary to market our product.

Certification:

Any product launched on the market undergo a process of evaluating its characteristics and verifying that it meets the technical and legal requirements of the target market. This confirmation is obtained through external review, assessment or audit. Depending on the industry and the intended use of the product, certification may cover one or more

characteristics and may be issued by different bodies. The main purpose of certification is to ensure the quality and safety of products.

Declaration of conformity:

The assessment of conformity with essential requirements is a mandatory legal action. The legislation of the relevant country clearly defines how this assessment should be carried out and confirmed. Depending on the legislation, it can be conducted either by the manufacturer or with the voluntary or mandatory involvement of a third party - usually a Notified Body. Certification is always an evaluation of the conformity of the subject with a reference document conducted by an independent third party. Certification can be mandatory (required by law) or voluntary (chosen by the manufacturer).

Conformity assessment always results in a declaration of conformity with the essential requirements. Certification ends with the issuance of a certificate. The certificate is not a declaration of conformity, but it can serve as the basis for the manufacturer to make such a declaration.

When designing the features of a new product, we need to determine which features will be assessed in the conformity assessment process and incorporate them into our product accordingly. If our product is subject to certification requirements, we must also consider the features required by the Notifying Body.

Note

Typically, conformity assessment and certification are based on documents prepared by the manufacturer. Therefore, before placing a product on the market, we should carefully consider what documents will be required for the declaration of conformity and product certification and prepare them accordingly.

In the case of marketing a product resulting from research in a scientific unit, it is the manufacturer's responsibility to obtain a conformity assessment and product certification. However, this does not relieve the research team of the obligation to identify the product characteristics to be assessed in these processes, as these characteristics must be integrated into the product during the laboratory testing stage and refined during the stage of increasing the product's readiness for implementation.

Each industry has typical market constraints!

The most stringent restrictions apply to medical devices. Depending on their intended use, they are divided into classes related to the safety of their use and their potential effect on the patient's body. Each medical device must undergo a certification process specific to its class. Certification can only be successful if the tests show that the product meets all safety standards and has proven specific therapeutic properties. The requirements for medical devices are contained in the MDR Directive or Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Products used for the treatment of animals are subject to Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medical devices.

Products used in cosmetics, on the other hand, are subject to Good Manufacturing Practices (GMP). GMP principles apply to all personnel involved in the production of the cosmetic, as well as to the premises and equipment of the production facility. GMP also places requirements on the raw materials used in production, the packaging in which the products are placed, and the way in which the cosmetics are stored and transported. Cosmetic products placed on the market must have a safety report and be notified to the CPNP (Cosmetic Products Notification Portal), a portal run by the European Commission.

To market a new chemical compound, we must comply with the REACH directive, i.e. Regulation No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals and establishing a European Chemicals Agency: Registration, Evaluation, Authorisation and Restriction of Chemicals. The legislation applies to all chemical substances, not only those used in industrial processes, but also those used in everyday life, such as cleaning products, paints, clothing and household goods.

Products used in the construction industry are subject to the Regulation of the Minister of Infrastructure and Construction of 17 November 2016 on the declaration of the performance of construction products and their marking with the construction mark. According to this act, the manufacturer declares the performance of a construction product, expressing it as a level, class or in a descriptive manner, based on the assessment and verification of the constancy of these performance characteristics carried out in accordance with a national system appropriate to the product and its intended use.

Part 3: Commercialization of the research results

3.1 Direct and indirect commercialization

3.1.1 What is the commercialization of R&D results?

Commercialization of research and development (R&D) results involves transforming R&D results into marketable products, technologies, services or solutions that generate profits. This process includes all activities aimed at applying research results into business practices, such as licensing, selling intellectual property rights, creating new products, establishing start-ups or expanding existing businesses.

Commercialization of scientific research and development results refers to any activity aimed at using and making available the R&D results in such a way as to generate financial benefits on a market basis.

An important aspect of commercialization is the collaboration between research organisations and enterprises, which maximizes the potential of science and innovation.

What can be commercialized?

Generally, commercialization is a broad concept that encompasses various activities aimed at offering goods or services on the market to generate revenue. When referring to commercialization in the strict sense, the focus is on innovations or research results. Commercialization in this narrower sense involves developing a product or service based on research outcomes.

It must be noted that generally available knowledge or results cannot be commercialized (in a strict sense) as such. If an invention is not patented and can be freely used by any entity, a business will not be able to build a competitive advantage solely based on that invention. The full benefits of innovations and research results can only be realized when access to such results is regulated, either through confidentiality agreements (know-how) or more importantly, through intellectual property rights. Therefore, the legal protection of innovations or research results is crucial for successful commercialization.

As it was previously explained in this curriculum (see chapter 1.), generally, the economical rights to the results belong by default to the author or inventor. However, under certain circumstances, the rights might be assigned by default to the employer or commissioner.

As a first step, before entering negotiations with a potential partner, it is essential to verify the legal status of the results. The transferor must be legally entitled to dispose of the results. Similarly, in the case of know-how, the commercialization entity must ensure that all individuals involved in its development are bound by confidentiality obligations. Therefore, it is important to establish and implement appropriate procedures for results handling and IPR and know-how management within such entities (see chapter 1) Additionally, before entering into any contract, due diligence must be conducted (see chapter 1).

The first condition that must be met for successful commercialization - an entity may commercialize results to which it holds rights, either proprietary rights (as the owner) or rights to use the results to an extent that enables commercialization (e.g., through a license granting the right to sublicense). If the results are not protected under intellectual property rights, their value depends on their confidential nature. Therefore, the commercialization entity must act diligently to maintain their secrecy, as the commercialization potential depends on keeping them confidential.

Note:

The commercialization entity must be the owner of the property rights in the commercialized result/solution!

Commercialization takes different forms depending on whether it is pursued by higher education institutions or business entities. Typically, commercialization conducted by HEIs is by national laws concerning the higher education system.

Relevant regulations in Greece

Law 2843/2000 does not explicitly define research results or specify which research results may be commercialized. Instead, it establishes the framework for the commercialization of research outcomes from universities, research centers, and businesses without providing a specific definition of what constitutes research results.

Greek legislation does provide specific definitions related to research results eligible for commercialization. Law No. 1733/1987, titled "Technology Transfer, Inventions, and

Technological Innovation", offers pertinent definitions and frameworks. According to Article 5 of this law, patents can be granted for any inventions that are new, involve an inventive step, and are susceptible to industrial application. The invention may relate to a product, a process, or an industrial application. This definition outlines the criteria that research results must meet to be considered eligible for commercialization through patent protection.

Additionally, Article 19 introduces the concept of a utility model certificate, which is granted for each novel and industrially applicable three-dimensional object with a definite shape and form, such as a tool, instrument, device, apparatus, or parts thereof, capable of providing a solution to a technical problem. This provision offers an alternative form of protection for certain types of research outcomes, thereby facilitating their commercialization.

Relevant regulations in Poland

In Polish law, commercialization of research results is a concept defined exclusively in relation to specific categories of research entities, namely public higher education institutions and research institutes. The latter category encompasses institutes operating under various legal frameworks, including institutes of the Polish Academy of Sciences, institutes of the Łukasiewicz Research Network, and sectoral research institutes supervised by individual government ministries.

However, it should be noted that the commercialization of research results at public higher education institutions constitutes merely one specific instance of a significantly broader concept of commercialization.

In accordance with the provisions of the relevant Polish law regulating higher education (Law of 20 July 2018 - Law on Higher Education and Science), the results of scientific activity and know-how related to these results may be commercialized. The modes of commercialization of knowledge have been defined within this legislation.

The Law does not specify the types of results that may be commercialized; however, it distinguishes a specific category of scientific activity results that are subject to special procedures regarding notification, the possibility of vesting rights to these results to the employee, and the division of revenue obtained from their commercialization (by either the public university or the employee, as applicable). The Law applies exclusively to scientific research results produced by an employee of a public university as part of their duties under an employment contract. This category includes the following:

1. The results of scientific research, being an invention, utility model, industrial design or integrated circuit topography, a bred or discovered and derived plant variety;
2. The results of development work or artistic creativity.
3. Know-how related to these results.

Public universities in Poland are obliged to adopt internal regulations for managing IPR developed at the university. Based on such regulations the catalogue of results subject to revenue-sharing obligations and special procedures for acquiring rights by employees may be extended, for example to include software or trademarks. However, if software or a trademark is created within development work (or, in case of a trademark, also artistic creativity), it falls under a category regulated by the Law on Higher Education and Scientific Research.

The following provides an overview of the commercialization pathway for research results at Polish public higher education institutions

In an ideal commercialization scenario, preliminary market research precedes the research activity itself, which significantly increases the likelihood of successful commercialization.

An employee who creates a research result is obliged to disclose it to the institution without delay, typically through the Technology Transfer Office. The employee is simultaneously subject to a statutory confidentiality obligation with respect to the result. Any publication of the result by the employee prior to the institution's decision on commercialization constitutes a breach of statutory obligations and may jeopardise the possibility of obtaining intellectual property protection.

Following disclosure, the institution analyses the legal status of the result and takes a decision on commercialization.

After the decision on commercialization an appropriate appropriate intellectual property protection is applied and the institution then determines the appropriate commercialization pathway – direct or indirect commercialization.

Under each pathway, the institution seeks an appropriate commercialization partner. In the event of direct commercialization, a commercialization agreement is concluded (transfer or licensing of rights). In the indirect commercialization scenario the results are contributed as an in-kind contribution to a spin-off company through a special purpose vehicle company.

The employee-creator is entitled to a share in the financial benefits derived from commercialization. Under the Act, the creator's share may not be less than 50% of the benefits, reduced by direct commercialization costs not exceeding 25% of those benefits. The institution's internal regulations may provide for more favourable terms for the creator.

Relevant regulations in Romania

In accordance with Romanian legislation, research results that can be commercialized are regulated by several legal acts, including Law No. 8/1996 on copyright and related rights, Law No 64/1991 on patents and Emergency Ordinance 100/2005 on the enforcement of industrial property rights.

The main types of research results that can be commercialized are Inventions (patents), Innovations and technical solutions, Products derived from research, software and algorithms, products and services derived from scientific research, Copyrights.

It is important to note that, in many cases, intellectual property rights over research results are governed by specific contracts between researchers and research institutions (universities, research institutes) or external collaborators. The use and commercialization of these results must comply with the terms of these agreements.

3.1.2 Ways of Gaining Ownership Over the Results by the commercializing entity

The methods for obtaining ownership of results depend on the type of intellectual property rights protecting them. The rules may differ depending on whether the result constitutes a patentable invention or a work protected by copyright. Furthermore, the type of contract binding the creator and the entity plays a crucial role, as the rules differ between employment contracts and commission contracts. It is vital to have the necessary agreements in place, clearly defined employment duties, and appropriate clauses included in commission or collaboration agreements. **General requirements for such contracts should be provided within the internal procedures concerning IPR management.**

It is important to emphasize that **moral rights** are non-transferable and therefore remain with the author or inventor. This is because the moral rights shall be independent from the **economic rights** and shall remain with the author even after the transfer of the economic rights. Economic rights, however, may be transferred. The default rules governing the ownership of intellectual property rights in the context of employment or commission primarily depend on national law. Generally, the default rules on the ownership of the IPR apply automatically. However, the parties in most cases can modify the default rules by including relevant provisions in their agreement.

A general overview of national default principles regarding the ownership of IPR in Greece, Poland, and Romania is presented below. If, under the applicable law, the economic rights to research outcomes do not automatically belong to the commercializing entity, it must acquire those rights through an appropriate agreement.

EU level

In general, the entitlement of an employer or commissioner to intellectual property rights developed under a relevant contract remains within the competence of national law. For example, the EPC states that if the inventor is an employee, the right to a European patent shall be determined in accordance with the law of the State in which the employee is mainly employed.
In the case of designs (*Directive 98/71/EC of the European Parliament and of the Council of 13 October 1998 on the legal protection of designs*) and Community designs (C*ouncil Regulation (EC) No 6/2002 of 12 December 2001 on Community designs*), a general rule applies: if a design is developed by an employee in the execution of his duties or following the instructions given by his employer, the right to the design shall vest in the employer, unless otherwise agreed or specified under national law.

On the other hand, with regards to computer programs, the rules determining the right holder to a computer program are harmonized by directive (Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs). If a computer program is created by an employee in the execution of his duties or following the instructions given by his employer, the employer exclusively shall be entitled to exercise all economic rights in the program so created, unless otherwise provided by contract.

Relevant regulations in Greece

- **Copyright (Law 1733/1987)**

In Greece, in the case of works created by employees in the execution of an employment contract, initial holder of the economic and moral rights in the work shall be the author of the work. Unless provided otherwise by contract, only such economic rights as are necessary for the fulfilment of the purpose of the contract shall be transferred exclusively to the employer.

For public sector employees, the employer automatically gets the economic rights to the work, but the creator keeps the moral rights (like being recognized as the author).

The economic right on works created by employees under any work relation of the public sector or a legal entity of public law in execution of their duties by operation of law transferred to the employer, unless provided otherwise by contract. Therefore, work created by researchers in the context of their contractual relationship with the research organization is therefore owned by the research organization, which has all the property rights in the project, i.e. the exploitation rights.

However, according to Article 4 of Law 2121/1993, the moral right, i.e. the recognition of the author, belongs to the researchers. This is because the moral rights shall be independent from the economic rights and shall remain with the author even after the transfer of the economic rights. Work created outside the execution of an employment contract is primarily owned by the researcher.

- **Inventions (Law 1733/1987)**

Creators' rights in Greece are regulated by Law 1733/1987 for inventions. Article 6 of Law 1733/1987 on the transfer of technology, inventions and technological innovation defines the three (3) types of inventions:

a. **«Independent invention»:** An invention carried out by a private independent inventor, without the means of the employer, and wholly owned by him.
b. **«Service invention»:** is the outcome of a contractual relation between the employee and the employer for the development of inventive activity. In case that a service invention is accomplished, the employee shall have the right to request an additional reasonable recompense if the invention is particularly profitable to the employer. The rights to the invention belong entirely to the employer. In order for an invention to be

classified as a service invention, it must be the result of a contract between an employer and an employee. It is irrelevant whether the contract is a contract for employment or an independent service contract.

c. **«Dependent invention»:** is the invention made by an employee with the use of materials, means or information of the enterprise in which he/she is employed. In this case, the invention is owned 40% by the employer and 60% by the inventor or group of inventors who made it. The inventor of the dependent invention shall without neglect notify in writing the employer on the accomplishment of the invention and shall give the necessary data for the filing of a joint patent application. If the employer does not answer in writing within four months form said notification to the employee that he is interested in jointly filing the patent application, the said application shall be filed by the employee only and in this case the invention belongs entirely to the employee.

Relevant regulations in Poland

The rules governing the default ownership of intellectual property rights are regulated by legal acts specific to each type of intellectual property. As a result, different principles apply to works, databases (sui generis rights), and industrial property subjects. These default rules can be modified through contractual agreements. Furthermore, specific regulations govern research results obtained by employees of higher education institutions.

The ownership of the copyright (proprietary rights) depends on the circumstances under which the work has been created by the author.

Type of work	The owner of the copyright
Independent work created by the author (a natural person)	The author
Work created under the employment contract	Employer, unless otherwise agreed in the employment agreement
Work created under a commission contract	Depends on the contractual arrangements – the author owns the copyright in the commissioned work unless otherwise agreed. It is necessary that the transfer agreement is made in writing.

Joint works	Joint ownership of the coauthors.
Collective works	Each author/owner has economic rights to separate works, however, if the arrangement of the separate works itself meets the copyright criteria, the author of such collective work is entitled to the copyright.
Derivative works	Separate copyright to the derivative work is vested in its author, however, the derivative work cannot be exploited or the copyright. to the derivative work cannot be disposed of unless the permission of the author of the original work is given.
Scientific works (a specific provision)	As an exception from the general rule governing the copyright ownership of the works created under employment contract, the author is the copyright owner, however, the research institution has priority to publish the scientific work.

Common Rules on Ownership of the Right to an Invention, Utility Model, and Design Right

Type of invention project (invention/utility model/design)	**The owner of the right**
Independent invention project created by the inventor/the author (a natural person)	The author/the inventor
Created under the employment contract	Employer, unless otherwise agreed in the employment agreement
Created under a commission contract	Ordering party, unless otherwise agreed in the agreement
Joint invention projects	Joint ownership of the co-creators
An invention project developed by the creator with the assistance of an entity (business undertaking)	The author/inventor, however, the entity may use the invention/utility model/design on its own account

Databases (sui generis right)

According to Polish law on the legal protection of databases, the sui generis right to a database is vested in its producer. The producer is defined as an entity that bears the risk of investment in the creation of the database.

Know-how

As explained in the previous chapter, the value of know-how is directly tied to its confidentiality. Know-how is not protected by an exclusive right, and therefore, it cannot be said that the right to know-how is vested in any specific entity.
Labour law obliges employees to maintain the confidentiality of information that, if disclosed, could expose the employer to harm or financial loss. Simultaneously, trade secrets are protected under the Law on Combating Unfair Competition. However, in all cases, the employer should implement appropriate confidentiality procedures, while a commissioner should include adequate confidentiality clauses in the commission agreement or execute a separate Non-Disclosure Agreement.

Plant variety

According to the Polish Act on Legal Protection of Plant Varieties, the exclusive right to a plant variety belongs to the breeder. If the variety has been developed under an employment or commission contract, the employer or the commissioner is considered the breeder by law; therefore, the right belongs to them.

Special provisions regarding research activity results of public university

The Law on Higher Education and Science provides special provisions governing specific procedures regarding research activity results obtained by an employee of a public university as part of their employment duties, provided these results fall into one of the designated categories of research outcomes. Under general rules, the rights to such results belong to the employer (the university); however, the author or inventor (the employee) may apply for the transfer of these rights to themselves. If the rights to the results are transferred to the employee and they commercialize these results, the university is entitled to a portion of the revenue generated by the employee from this commercialization.

Relevant regulations in Romania

The right to the patent belongs to the inventor or his successor in rights. If the invention was created by several inventors, each of them has the quality of co-author of the invention, and the right belongs jointly to them.

Under Romanian law, intellectual property created by employees during their employment is generally owned by the employer, but this is contingent on specific conditions. The relevant legal framework includes:

- Law No. 8/1996 on **Copyright and Related Rights**, according to this law any works created by an employee during the course of their employment that fall under the scope of the employee's duties, or the contract of employment may have their economic rights transferred to the employer. This is often specified in the employment contract.
    - In the absence of a contractual clause to the contrary, for works created in the performance of the service attributions specified in the individual employment contract, the economic rights belong to the author of the created work. In this case, the author may authorize the use of the work by third parties, only with the consent of the employer and with the reward for the contribution to the costs of creation. The use of the work by the employer within the scope of the activity does not require the authorization of the author employee.
    - If there is a contractual clause, it must specify the period for which the economic copyright has been assigned. In the absence of a specified term, the default duration is three years from the date of delivery of the work
    - In the event that there is a contractual clause, it shall include the term for which the copyright (economic rights) have been ceded. In the absence of the term, it shall be three years from the date of handing over of the work.

- **Inventions:** Inventions created by employees in the course of their work typically belong to the employer, unless the employment contract stipulates otherwise. If the invention is made outside the scope of regular duties, the employee may retain ownership, but the employer often retains an option for licensing or acquiring the rights.

- The right to inventions resulting from the exercise of the inventor's duties belongs to the employer, in the absence of a contractual provision to the contrary, if he is a public-law person and has in his object of activity research and development.
- The right to inventions which have been obtained, during the individual employment contract, and for a maximum period of 2 years from its termination, as the case may be, by knowing or using the experience of the employer by using the material means of the employer, as a result of the training and training acquired by the inventor employed by the care and at the expense of the employer or by using information resulting from the work of the employer or made available by him belongs to the employer of private or public law that claims the invention within 4 months from the communication of a notice from the employee, the, if a longer term is not provided for in the employer's internal rules. The employee who creates an invention has the obligation to communicate immediately to the employer the presentation of the invention, in which to describe the solution of the problem solved with data clear enough to define the invention and the conditions under which the invention was created.

The right to inventions created by employees and which do not fall under any of the above situations belongs to the inventor of the employee, under the conditions provided by Law no. 64/1991 on patents for invention.

- Law no. 83/2014 regarding **service inventions** applies to inventions created by an individual inventor or a group of inventors, the individual inventor or at least one member of the group of inventors is an employee of a legal entity under public or private law.

In accordance with the provisions of Law no. 199/2023 of higher education, the protection of intellectual property rights on scientific creation, the, cultural or artistic is guaranteed and is ensured in accordance with the provisions of the university charter and the specific legislation in force.

Universities and Research Institutes: In Romania, the law recognizes the importance of research conducted at universities and other public institutions. The university may claim ownership of IP produced by researchers in the course of their work, but this typically depends on the terms of employment or collaboration agreements.

- **Research Contracts**: Universities and public research institutes often have agreements with researchers or third-party entities (e.g., private companies, government bodies) that define the terms of IP ownership. These agreements might include clauses for licensing, commercialization, or patenting of results.
- **Public Sector R&D**: For publicly funded research projects, the economic rights to the results might belong to the institution, or the public body funding the research, depending on the specifics of the agreement. In some cases, the rights might be shared between the researcher and the public institution.
- **EU Regulations and Contracts**: If the research is part of an EU-funded project, the terms of IP ownership may be governed by the specific regulations of the funding program (e.g., Horizon 2020 or Horizon Europe). These regulations typically set out the conditions under which IP is managed, owned, and exploited.

- **Employment Contracts**: The transfer of economic rights (including rights to inventions, designs, and other IP) to the employer is often explicitly stated in the employment contract. If the employment involves research and development, it is common to include clauses addressing the ownership and exploitation of results.
- **Collective Bargaining Agreements**: In certain cases, there may be specific agreements in place between employers and employees that outline the treatment of IP created during research activities.

The results of the research obtained on the basis of a research-development or innovation contract financed partly or totally from public funds belong to the contractors who directly perform the activities stipulated in the financing contract and/or their employees, according to the financing contracts and the legislation in force regarding the industrial property titles and the copyright. In the case of execution by several contractors, the distribution of the rights to the results between the contractors shall be made according to the prior agreement of the contractors, established in writing. The results of the research are administered by their owners, with all the rights deriving from the ownership. The documents, collections and databases of national interest, as well as the units or institutions in whose custody they are kept are established by order of the head of the state authority for research and development. At the level of the state authority for research and development is established and kept the register of documentations, collections and databases of national interest.

3.1.3. Paths for commercialization of R&D results

Commercialization can be undertaken by both the academic and industrial sectors. In the case of enterprises, commercialization primarily focuses on gaining financial benefits from their intellectual assets. This can be achieved by directly implementing R&D results into the business operations or by licensing or selling intellectual assets to other entities. There are two main categories of commercialization: direct and indirect. These concepts are associated with both higher education institutions and business entities; however, the rules applicable to each sector differ.

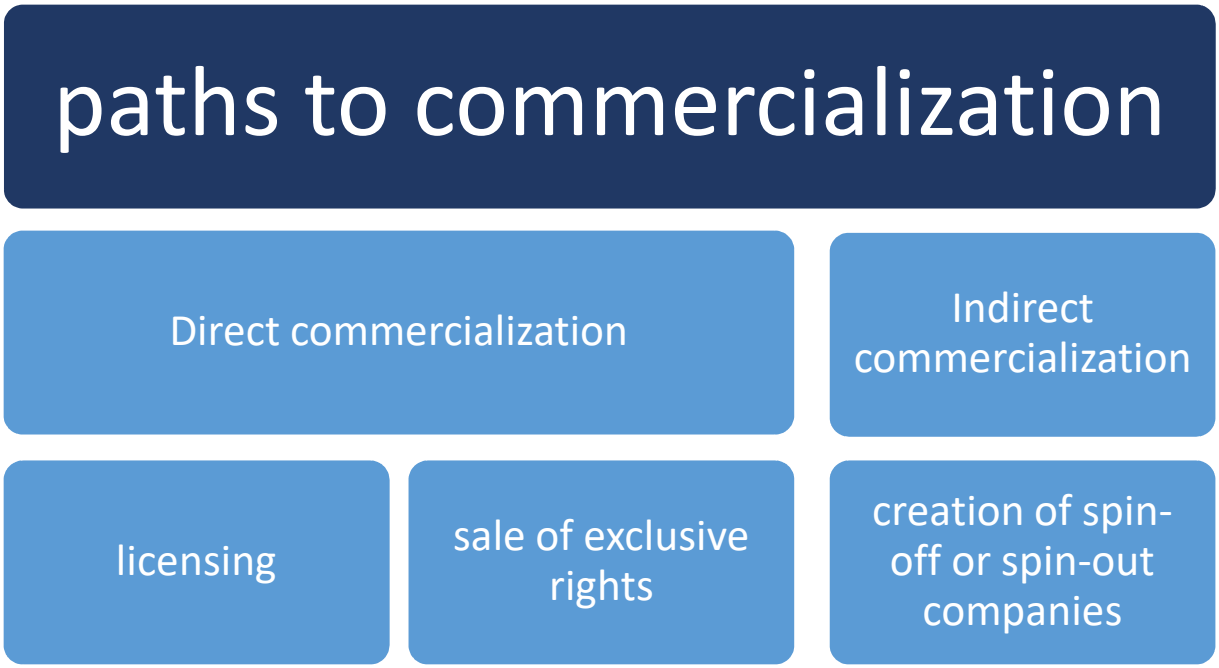
Direct commercialization is carried out directly by the university or other entity (for example enterprise) involving the sale of the results of scientific activities or related know-how, or granting their use to third parties through licenses, leases, or rental agreements

Indirect commercialization is carried out by the special purpose vehicle involving subscribing to or acquiring shares in companies or subscription warrants giving the right to subscribe to or acquire shares in companies in order to exploit or prepare the exploitation of the results of scientific activity or the know-how related to those results.

Indirect commercialization is the creation of start-ups (spin-off, spin-out) - for example employees of a university or research institute may create companies (start-ups) that use the research results to bring innovative products or services to the market. Start-ups use solutions developed at universities or research institutes, usually under license agreements.

Note:

As explained above, solutions created by employees within their employment duties are the property of the employer e.g. university or research institute. Therefore, the start-up must buy or license these solutions from the university, or the university may make an in-kind contribution of research results to a start-up (e.g., through a special purpose vehicle, SPV) in exchange for equity in the start-up!



3.2 Assignment of rights to the results (direct commercialization)

3.2.1 What is the result of R&D work?

The result of R&D work is the outcome of a research project carried out in a university, an enterprise or a research unit; this outcome can be intellectual property or know-how. The result of R&D work can be any result (tangible and intangible) product generated by the project, but not all results may be suitable for commercialization.

Note:

The assignment of rights to R&D results is the process by which a right holder (for example university or research unit) transfers all its rights to the R&D results to the buyer, who then becomes the sole owner of those results.

This full transfer of property rights to exploit the results commercially, allows the buyer freely use the R&D results, including implementing the results in the market, modifying them, or granting licenses to other entities.

The assignor (for example a university) loses the right to dispose of the solution but usually can continue further research and development.

The sale of rights to R&D results may include the transfer of copyright, industrial property rights (such as patent applications, patents, utility models) and other forms of intellectual property to the buyer. From the buyer's perspective, purchasing the rights to R&D results allows for the full exploitation of their commercial potential.

A special case is the of know-how "transfer"

Know-how is technical or non-technical knowledge (commercial, administrative, organisational, financial) useful for conducting a particular type of business. Know-how is protected by keeping this knowledge secret and is not protected by an exclusive right. Its value derives from the limited accessibility of the knowledge. Therefore, it cannot be sold (in the strict sense) but can only be authorized for use in business activities through a know-how agreement.

3.2.2. Terms and conditions of contracts for the transfer of rights to R&D results (direct commercialisation)

The contract for the transfer of rights to R&D results must clearly define the scope of the rights transferred to the buyer and the obligations of both parties.

- **Form of the agreement**

Under national laws, it may be required that an assignment of intellectual property rights (e.g., industrial property rights, copyright, plant variety rights) be in written form to be valid. Such a requirement is typically imposed by the applicable national law governing the specific category of intellectual property rights.

- **Representations of the parties**

The representations of the parties section in an assignment agreement usually includes key statements and guarantees made by the parties. The assignor may declare that they have full legal authority to transfer the R&D results, that the results are original, and that they do not infringe the rights of third parties. If an application for granting a right has been filed, the assignor may declare that the application has been duly submitted and is pending before the relevant patent office. The assignee may affirm that they have conducted their due diligence on the transferred right and accept its current status. In the case of an application for a right, the assignee may confirm that they are aware of the uncertainty regarding the granting of the right.

- **Subject matter of the contract**

The precise definition of the subject matter of the contract is very important. The contract must precisely define the research results being transferred. If research results are protected under intellectual property rights, the transfer of rights should be explicitly stated in the agreement. It is worth emphasizing that transferring tangible goods, such as a work or a prototype, does not include the transfer of intellectual property rights, such as copyright or the right to obtain a patent.

If the subject of the contract is an industrial property right application or an already granted right, the relevant application documents should be annexed to the contract.

In the case of industrial property rights, the assignment concerns the entire right within the relevant territory where the right is granted. This contrasts with a license, which may allow the use of the right in a limited way, for example, within a specified territory (region), or within a particular sector.

Regarding copyright, each economic right to a work may be transferred separately. In some countries, a transfer agreement must specify each economic right individually for the transfer to be valid. Moreover, each right may be transferred within a specified territory, for a specific application, or within a particular sector.

- **Remuneration**

Lump sum fee - In most cases, the sale of rights to R&D results involves a one-off payment of a fixed amount. The fee depends on the potential market value of the results, the cost of the research and the chances of commercialisation.

Staged or additional payments - in some cases a staged price is set or the buyer may commit to additional payments based on the success of commercialising the results.

- **Indication the moment of transfer of the R&D results**

The moment of the transfer of rights may be specified in the agreement. For example, from the seller's perspective, it may be convenient to stipulate that the transfer of rights occurs at the moment when the full remuneration for the transfer is credited to their bank account. On the other hand, the assignee would prefer that the transfer of rights occurs at the moment of signing the contract.

- **Creators' rights**

Creators of R&D results (e.g. an inventor or an author), such as scientists who have contributed to the invention, retain their moral rights. This means that they have the right to be named as the creator of the invention or work, even if they transfer the ownership of rights to another party. An obligation to respect such rights may be included in the agreement, which may also specify the manner of their implementation (in a manner formally accepted by the creator). While moral rights are not transferable, they may be subject to certain obligations.

For example, the right of first communication to the public may be addressed in the agreement through a relevant statement by the author, agreeing that the assignee may choose the timing and circumstances of such communication. Another example may be the obligation to refrain from exercising moral rights related to supervision over the work. Moral rights are not harmonized at the EU level; both examples provided are based on the Polish legal framework.

- **Possibility of using the subject matter of the assigned rights by the assignor**

The contract usually provides for the transfer of full economic rights to the R&D results to the assignee (buyer), meaning the assignor does not retain any rights to exploit the results

commercially. If the assignor wishes to use the work or invention to which the rights have been assigned, they must be authorized by the new owner of those rights. This is usually done through a so-called back license. As a consequence, the IPRs are transferred to the acquirer, and the acquirer grants a license to use those rights to some extent to the seller. For example, a small enterprise may transfer a patent to another entity while still produce and sell goods incorporating a patented invention in the current scale and territory.

It must be underlined that most national laws allow the use of protected intellectual property for purposes not related to commercial exploitation. This possibility arises from the scope of protection granted to a given type of IP. For example, depending on national law, a patent usually grants an exclusive right to commercially or professionally use an invention, while copyright provides a monopoly over specific activities such as reproduction, distribution, and communication to the public. Therefore, activities not covered by these exclusive rights are generally permitted.

Moreover, each legal system expressly defines exceptions and limitations to intellectual property rights, such as: private or non-commercial use; experimental use or scientific research; exhaustion of rights; fair use in copyright.

As a result, a given work or invention may be used based on a specific exception provided by law. For example, a patented invention may generally be used for research and experimental purposes without requiring authorization. However, a university or research institution may additionally include provisions in the contract allowing further use of the solution for scientific or teaching purposes.

- **Maintenance of protection**

The contract may include provisions for further patenting of the invention or maintaining its protection. The assignee steps into the seller's shoes and assumes the obligations related to the procedure for granting the intellectual property right and its maintenance. The buyer is required to pay for relevant fees and other costs associated with intellectual property protection.

- **Infringement clauses**

The contract may outline actions to be taken if third parties infringe on the rights to the assigned IP. The buyer may be required to take legal action to protect its rights and the seller may be required to cooperate in such situations.

- **Maintaining confidentiality**

A contract for the transfer of rights to R&D results often includes confidentiality clauses regarding the technology and information relating to the invention, especially in situations where the sale involves results that have not yet been patented.

- **Further development of the technology - research cooperation**

In some cases, agreements may provide for further cooperation between the parties in the development of the technology. Typically, the implementation of the technology will require implementation assistance from the inventors, which may involve research or consulting cooperation.

- **Penalties and termination clauses**

Penalties for breach of contract: The contract may provide for financial or other penalties in the event of a breach of contract, if one of the parties fails to meet its obligations (e.g. deadlines for providing additional documentation, confidentiality).

- **Rescission of the contract**

The assignment is a transfer agreement with a permanent effect. Unlike licenses, the termination of an assignment is possible only in rare cases, as governed by national laws. However, the agreement may include provisions specifying the conditions under which the contract may be “cancelled”, such as failure to pay the contractual remuneration. Any such possibility should be linked to a clause defining the moment of the transfer of rights.

- **Change in the relevant register**

In the case of registered rights (e.g., patents, design rights), it may be necessary under national laws to record a change in the relevant rights register for the agreement to be effective against third parties (not involved in the assignment). Notification to the registry is usually made by the assignee, as disclosing information about the new rights holder in the register serves their interest.

- **Dispute resolution, governing law and jurisdiction**

The agreement should establish a clear procedure for resolving disputes between parties. This may follow a stepped approach:

1. Internal resolution - parties first attempt to reach agreement through internal negotiations.
2. Mediation - if internal resolution fails, a neutral mediator is engaged.
3. Arbitration or litigation - if mediation is unsuccessful, disputes are referred to arbitration (e.g. WIPO or ICC) or the competent national court.

Governing law refers to the substantive law that governs the interpretation and performance of the agreement, including consequences of breach or non-performance. Ir is always law of a determined country.

Jurisdiction refers to the body competent to adjudicate disputes - this may be a national court (which can be specified down to city level, e.g. the seat of one of the Parties) or an arbitral tribunal. In practice, international agreements often exclude national court jurisdiction in favour of arbitration.

Consistency between the chosen governing law and jurisdiction is essential. A mismatch may result in a court applying foreign law, which increases complexity and uncertainty.

Advantages and disadvatages of an assigment

Assignor (seller)	**Assignee (buyer)**
The seller receives the full payment upfront, providing immediate financial benefits.	The buyer obtains all rights related to the IP, allowing full control over it, including modifications, sales, or licensing.
The seller is relieved of the responsibility of managing intellectual property rights and maintaining legal protection.	If the IP generates high future revenues, the buyer does not have to pay royalties to the seller.
The original owner loses all rights to the IP, which could be disadvantageous if the IP proves to be highly profitable in the future.	An IP transfer agreement usually requires a one-time, often substantial payment, which must be proportionate to the potential value of the IP.
The transaction is typically irreversible, meaning the seller cannot reclaim rights even if business circumstances change.	The buyer must manage intellectual property, including maintaining legal protection (e.g., renewing patents or trademarks).

3.2.3. License agreement (direct commercialization)

What is a License?

A license is a contract that allows others to use the results of R&D developed by the commercializing entity (e.g., a university or research institute). Under the license, the entrepreneur gains the right to manufacture and market products based on the licensed solution. In this way, the rights holder shares the risks and benefits of exploitation the results with one or more licensees. A license agreement is concluded for a specified period of time.

License types:

- **Full license**

A full license means that the licensee has the right to use the licensed solution to the same extent as the licensor (owner). A full license means that the licensee is granted the right to use the invention, technology or R&D results to the full extent provided for in the legal protection (e.g. in a patent or copyright). In practice, the licensee can use the invention to the same extent as the owner (licensor) and the licensor does not restrict this use.

> *Example: The university grants the company the right to fully exploit the invention in production, sales and further development, covering all economic sectors and markets.*

- **Restricted (incomplete) License**

A restricted license limits the extent of the licensee's right to use the technology in relation to the licensor's rights. The license agreement specifies the areas of restriction. Restrictions may relate to subject matter, time or territory. A restricted license may provide that the invention may only be used in a particular industry (e.g. medicine), for a specific activity (e.g. solely for production, excluding the right to trade the products) or in a particular territory (e.g. Europe). The period of use may also be limited, e.g. to a few years.

> *Example: The company receives a license to use the technology only in a specific sector, such as medical device manufacturing, for a period of 10 years.*

- **Exclusive license**

An exclusive license gives the licensee the exclusive right to use the invention or R&D results to a certain extent. This means that the licensor is not allowed to license the same invention to others or to use the invention itself within the agreed scope. The licensee becomes the only

entity that can use the invention in a particular field (e.g. geographical area) or industry. By granting an exclusive license, the licensor loses the right to further exploit the invention within the specified scope.

> *Example:* *The university grants the company an exclusive license to use the technology to produce the new material exclusively for the construction industry in Europe. The university may not license the same invention to other companies or use it itself in this field (e.g., provide services based on the licensed patent).*

- **Non-exclusive license**

A non-exclusive license is a license that allows the licensee to use the invention, but at the same time allows the licensor to license others and to use the invention itself. A non-exclusive license does not give the licensee a monopoly on the use of the invention. This means that the licensor can continue to use the invention himself and license others.

> *Example:* *The university grants non-exclusive licenses to several companies to use the invention in the same regions or sectors, while continuing to provide services based on the licensed patent itself.*

- **Implied license**

A license that arises from the conduct of the parties rather than from a formal contract. The possibility of granting an implied license must be based on national law. This is a situation where the licensing party implies that the licensee has the right to use the invention even though no formal license agreement has been signed. For example, if national law recognizes the concept of an implied license, such a license might be granted when university conduct research under an R&D contract. In the absence of other provisions in the contract, the client may receive an implied license to use the results of the R&D covered by the contract. It should be noted that the client does not become the owner of these results but only has the right to use them in its business.

An implied license may arise, for example, from a long-standing collaboration between the parties where one party provides the technology and the other uses it, although there is no formal agreement.

- **Sub-license**

A license granted by a licensee to a third party to use an invention or technology on the basis of the main (primary) license obtained. Sub-licenses may only be granted if the primary license

provides for this possibility. The scope of the sublicense is restricted by the scope of the primary license.
A licensee who has obtained an exclusive or non-exclusive license may grant sub-licenses to others if authorised to do so by the licensor. In a sublicense contract, the licensee of the primary license assumes the role of a licensor. A sub-license is usually subject to the same restrictions as the main license.

> *Example:* *A company that holds a license to a patented technology sublicenses it to another company so that it can manufacture products based on that technology in a region that it does not directly affect.*

The results of research and development (R&D) are often protected by intellectual property rights such as patents, utility models or copyrights. To enable their use in business practice, licenses may be granted to allow others to use these results under certain conditions. There are several types of licenses, varying in the scope of rights and conditions of use.

Specific cases of licenses

- **Trial license**

A trial license gives the user the right to temporarily test or use the results of the R&D work (e.g. software, technological prototype, tool). It is intended to enable a potential licensee to assess the functionality, usefulness or effectiveness of the invention or software to the full extend before deciding whether to purchase or fully license it. It is usually of limited duration and may also be limited in scope. Under a test license, the licensee may not commercially exploit and profit from the technology.

- **Demo license**

A demonstration license is a license granted to demonstrate the capabilities of a technology or product in a limited or specially prepared version for demonstration purposes. Its purpose is to demonstrate the capabilities of the technology to potential customers, investors or partners without granting full access to the technology or the ability to implement it. This is typically a license license used for marketing purposes, e.g. at trade shows, exhibitions or customer presentations. In the case of R&D work, a demonstration license may show the

capabilities of an invention, but without full functionality and without access to the source code.

- **Conditional license**

A conditional license is a license granted subject to certain conditions. As a consequence of fulfilling the condition, the agreement may come into effect (condition precedent) or, alternatively, may result in the termination of the agreement (condition subsequent). For example, a license may be granted subject to the successful completion of tests, the obtaining of relevant certificates or the achievement of certain commercial results. Another example would be a license conditional on subsequent development or implementation work.

Terms and conditions of license contracts

- **Representations of the parties**

The representations of the parties section in a license agreement, as in the case of an assignment, includes key statements and guarantees made by the parties. The licensor should declare that they have full legal authority to license the R&D results and that executing the agreement does not infringe on the rights of third parties.
The licensee may affirm that they have conducted their due diligence on the licensed right and accept its current status.

- **Subject matter of the license**

As with assignments, the precise definition of the subject matter in a license agreement is crucial. The licensed rights must be clearly identified. For instance, if the right to a patent application is the subject matter of the license, details such as the application number, filing date, and the relevant patent office should be specified, and the application should be annexed to the agreement. Similarly, if the subject matter of the license is know-how, a detailed description of the confidential information should be included as an annex to the agreement.

- **Scope and duration of the license**

As explained above, a license may be limited in various ways, making it essential to define the scope of the license with precision. The agreement should specify the territory, exclusivity, duration, and other limiting factors, such as the designated sector or specific activities (e.g., production, marketing, or distribution of products). In the case of industrial property rights (such as patent), unlike in the case of an assignment, a license can be limited to very specific activities.

A license cannot be granted for a period exceeding the duration of the underlying intellectual property right (e.g., after a patent has expired). However, certain obligations may extend beyond this period, such as the exploitation of know-how that complements the core patent license or the provision of services accompanying the license.
In such cases, it is crucial to clearly define the remuneration for each component of the license separately to ensure transparency and proper allocation of payments.

- **Type of the licesnse granted**

The agreement should explicitly specify the type of license granted, for example, an exclusive license, a sole license, or a non-exclusive license. The type of license granted may be deduced from the terms of the agreement; however, it is always better to state it explicitly to avoid any doubts.

- **Remuneration**

Royalties in license contracts are one of the key elements that determine the terms of use of the technology by external parties. Setting these royalties is a complex process that depends on several factors, such as the commercialization potential of the R&D results, their uniqueness or breakthrough nature and how they can be used by the licensee. The license agreement should precisely specify the method for calculating royalties, payment deadlines, and any reporting requirements the licensee must fulfil to ensure transparency regarding the contractual remuneration. Here is an overview of the types and principles of royalty setting:

Types of royalties

1. **Initial fee**

This is a one-off fee (lump sum) paid at the start of the license agreement (initial down payment). Usually represents compensation for the transfer of the right to use the invention. Determined on the basis of the market value of the invention, the expected profits and the research and development costs incurred by the licensor.

2. **Periodic payments**

Regular payments, which may be based on specific dates (e.g. annual fees) or on the achievement of specific milestones in the development or commercialization of the invention. They work well for long-term projects where the invention requires further development or adaptation before full commercialisation. Usually, recurring payments are structured as

percentage-based royalties or per-unit fees; however, it is rare for parties to agree on recurring lump sum payments.

3. **Percentage– based royalties**

A fee calculated on the basis of a percentage of sales of products or services using the licensed invention. Most commonly used in agreements where the licensee makes and sells products using the invention. Can be set as a percentage of net sales (e.g. 5% of net sales). Typically ranges from 1% to 10% but can be higher for very innovative and unique technologies; the level of royalties depends on the industry in which the technology is used.

4. **Per-unit royalties**

Per-unit payments are fixed amounts paid by a licensee to a licensor for each defined quantity (unit) of products (or services) that are produced, marketed, or sold, or otherwise used, as defined in the agreement.

5. **Minimum fees**

Minimum amounts that the licensee must pay regardless of the number of actual sales. They protect the licensor from a situation where the invention generates no revenue. Provide the university with a minimum return on its research investment, even if commercialization is slower than expected. Depends on the market value of the invention and the expected revenues of the licensee.

6. **Fees for sub-licenses**

If the license permits the licensee to grant sublicenses, the parties should clearly define the terms under which a sublicense may be granted, particularly the conditions regarding royalties owed to the primary licensor as a result of the sublicense. These royalties ensure that the original licensor receives a share of the revenue generated from the sublicenses. The amount typically depends on the terms set forth in the primary license agreement and the anticipated revenues from the sublicense. Such fees may be defined as a fixed amount, a percentage of the revenue generated by the sublicensee (royalty-based), or a combination of both.

Note:

The first step in determining royalties is to value the technology!

There are a number of factors to consider when setting fees:

- **Technology Readiness Level** (TRL) - the higher the TRL, the higher the value of the license;
- **Competitiveness and uniqueness of the invention** - the more unique and difficult to substitute, the higher the market value;
- **Potential market** - licenses for inventions that are likely to be widely used in a large market will have higher fees;
- **Risk sharing** - Universities sometimes use flexible royalty models that depend on the success of commercialisation. For example, they may charge lower initial fees and higher fees if the licensee achieves high sales returns;
- **Research and development costs** - fees should be set at a level that allows the university to recover at least some of the costs associated with developing the invention. This includes both direct research costs and the cost of legal protection;
- **Innovation-related clauses** - some agreements may include clauses for further development of the invention or joint research with the licensee, which may affect the fee structure.

Fees may vary depending on license type:

- Exclusive license: usually involves higher fees because the licensee has the exclusive right to use the licensed R&D result.
- Non-exclusive license: If the license is granted to several parties, the fees may be lower because the invention is available to a wider group of companies.
- License term - long-term licenses may have lower annual fees but higher one-off fees.

Note:

Setting royalties is a complex process that requires a thorough understanding of both the potential of the technology and the financial capacity of the licensee, as well as a flexible approach to negotiation that takes into account the interests of both the university and the commercialising companies.

- **Obligations of the licensor and the licensee**

The license agreement should clearly define the obligations of both parties. The licensor is typically obligated to:

- provide the licensee with the necessary documentation to implement the licensed technology,
- maintain the legal protection of the licensed technology (e.g., by paying patent maintenance fees),
- defend the licensed IPR against third-party infringements and validity challenges (e.g., in cases where a third-party files for patent invalidation).

The licensor may provide additional services, such as assistance with the implementation of the technology, conducting additional tests, or offering consulting services. Any of these activities may affect the contractual remuneration.

The licensee, on the other hand, generally commits to:

- take the necessary steps to successfully commercialize the licensed technology,
- maintain transparent financial records and grant the licensor access to those records when required,
- use the licensed IPR strictly in accordance with the provisions of the license and avoid exceeding its authorized scope,
- inform the licensor of any detected infringements of the licensed IPR.

- **Possibility to grant sublicense**

If the parties decide to grant the licensee the right to conclude further licenses with third parties (sublicensing), the agreement must include clauses explicitly stating this right. In such a case, the royalties derived from sublicensing should be defined, and relevant reporting clauses should be included.

The license agreement may also impose additional conditions or restrictions on sublicensing. For instance, the license agreement may limit sublicensing to specific geographical regions or impose quality control standards on sublicensees to ensure compliance with the original license agreement.

- **Contractual penalties**

The agreement may include provisions for penalties in the event of a breach of contract. Such penalties serve as an additional sanction to encourage the parties to fully comply with the terms of the agreement. For instance, the parties may agree that the licensor will be entitled to a penalty if the licensee fails to take all the necessary steps (as defined in the contract) to implement the technology.

- **License term**

A license is a fixed-term contract whose duration is limited to the duration of the licensed right (for example, a patent or copyright). If the licensed right expires, the agreement loses its subject matter and terminates. However, license agreements may include certain clauses that remain in effect beyond the expiration of the right, such as confidentiality, or reporting.

It is also possible for a license to partially expire. For example, if several patents are licensed and one of them expires, the license may still remain valid for the other patents. Similarly, if a license covers both a patent and know-how, the license may expire for the patent while remaining valid for the know-how.

- **License termination**

National laws may impose restrictions on the termination of fixed-term contracts, such as a license agreement. Typically, both parties are entitled to terminate the agreement under certain circumstances provided by law, such as a breach of contract by the other party.

The license agreement should clearly define the conditions for its termination and outline the resulting consequences. Termination generally requires official notice. The contract should specify a notice period, meaning that the license will terminate after a defined period of time following the delivery of the termination notice to the other party. Contractual provisions may also allow for termination throughout the license's duration without the need to meet specific conditions. Conversely, the ability to terminate may be subject to limitations. For instance, the parties may agree that the licensor may terminate the agreement if the licensee fails to bring a product implementing the licensed invention to market.

- **Dispute resolution, governing law and jurisdiction**

The agreement should establish a clear procedure for resolving disputes between parties. This may follow a stepped approach:

4. Internal resolution - parties first attempt to reach agreement through internal negotiations.
5. Mediation - if internal resolution fails, a neutral mediator is engaged.
6. Arbitration or litigation - if mediation is unsuccessful, disputes are referred to arbitration (e.g. WIPO or ICC) or the competent national court.

Governing law refers to the substantive law that governs the interpretation and performance of the agreement, including consequences of breach or non-performance. Ir is always law of a determined country.

Jurisdiction refers to the body competent to adjudicate disputes - this may be a national court (which can be specified down to city level, e.g. the seat of one of the Parties) or an arbitral tribunal. In practice, international agreements often exclude national court jurisdiction in favour of arbitration.

Consistency between the chosen governing law and jurisdiction is essential. A mismatch may result in a court applying foreign law, which increases complexity and uncertainty.

Advantages and disadvantages of licensing

Licensor	**Licensee**
Stable licensing income.	Access to innovative technologies without the need to develop them in-house, reduction of costs.
Strengthened relationships with industry, market expansion – allows the licesor to enter new markets.	Reducing time to market.
Increased scientific visibility and potential research partnerships.	Formalities regarding the maintenance of IP protection burden the licensor.

The licensor retains IPR and, depending on the type of license, may continue using the licensed IP in its own business or even license it to multiple entities.	No need to pay remuneration equal to the value of IP upfront.
Contract management, ongoing compliance monitoring, enforcement, etc.	Usually, there is a possibility to terminate the agreement if the license is not profitable or no longer needed.
	Higher risk due to dependence on the licensor, who remains the owner of the IP.

3.3. Creator-entrepreneur, i.e. the application of project results in one's own business (indirect commercialisation)

A common practice among growing companies seeking new revenue streams and market opportunities is the creation of **spin-offs**. This solution has many advantages, as smaller units, separated from the organisational structure of the main business unit, can focus on specialised areas of activity or actively acquire new customers. This model is often used to implement research and development, innovative solutions, new products or services.

> *Definition*
> *Generally, a **spin-off** is a company that is separated from a parent company in connection with its research and development. Such an entity has a certain degree of autonomy, and the parent company must agree to its creation. The new entity is often legally and economically separate from the parent company.*

This model also works well in the public sector. However, in order to avoid financial and economic risks, universities or research institutes carry out this task through special purpose vehicles (SPVs), i.e. separate entities set up by the research unit to carry out **indirect commercialisation.** Thanks to this procedure, the university or research unit is not burdened with the financial and economic risk associated with the development and implementation of innovative solutions.

Definition

Indirect commercialization *- This means taking or acquiring shares in companies or subscription warrants entitling one to take or acquire shares in companies for the purpose of implementing or preparing to implement the results of scientific activities or know-how related to such results. In Poland, defined by the Act on Higher Education and Science of 20 July 2018.*

The main purpose of the SPV is to create and acquire shares in spin-off companies created to exploit R&D results or know-how developed at the university or in scientific and research units.

Definition

A Special Purpose Vehicle *(SPV) or Special Purpose Entity (SPE) is usually a limited liability company or limited partnership established for a specific, narrow or temporary purpose and to exclude financial, special tax or regulatory risks.*

Source of definition: Regulation (EU) No 549/2013 of the European Parliament and of the Council of 21 May 2013 on the European system of national and regional accounts in the European Union Place of publication: (OJ EU L 174, 26.06.2013, p. 1, as amended).

There are two types of spin-offs from universities and research institutes. Both types of companies provide an excellent opportunity for the successful implementation of innovative technologies developed by scientific researchers. They differ in the degree of linkage between the company and the university. The first type is a **spin-off** company, which is organisationally, formally, or legally dependent on the parent company. The second type is a **spin-out** company, which is completely independent of the parent company. Both types of enterprise are created by researchers in order to commercialise an invention or technology developed in the research unit.

Definition for academic terms

A spin-off *is a company created by at least one academic staff member, doctoral candidate or student for the purpose of commercialising and implementing technologies developed at the higher education institution and which is dependent on the parent company in organisational, formal legal, financial or infrastructural terms. A company set up in this way may use the intellectual property of the higher education institution on the basis of a relevant licensing agreement, a sales agreement or an in-kind contribution to the company.*

> ***A spin-out*** *is a company set up by at least one university employee, postgraduate or student to commercialise and implement the university's intellectual property independently of the parent company. Although a spin-out usually has no personal or capital links with the university, cooperation between them is usually established on market terms. It may use the university's intellectual property on the basis of a licensing or sales agreement.*

With the help of these companies, the university research unit can commercialise the results of its research and thus attract new investors. Such a company uses the intellectual property of the parent company based on a separate agreement that defines the principle of use of the intellectual property. This may be a licensing agreement, a sales agreement or, in the case of a spin-off company, the university/research unit may contribute this property in kind to the company. The choice of the appropriate business model is entirely individual and depends on market, capital and human factors.

3.3.1. Spin-off company

It is important to remember that the process of creating a spin-off requires a great deal of effort. First of all, it is necessary to identify the strategic objectives of the company, develop a business plan for the company, and identify sources of funding until revenues are generated from the implementation. In most cases, the spin-off will be a public or private limited company.

The creation of an academic spin-off company by a scientist or a team of scientists working on a topic in which they have strong expertise is a proposal that often appears in commercialization strategies and funding programmes for innovation projects. This model of commercialization has a number of advantages, but it can also be challenging. Some of the companies created by scientists do not succeed in the market or face various difficulties. In such a start-up, the originator/researcher always has the main substantive role, but is often required to have the business skills necessary to manage and develop the company properly.

Advantages of the spin-off company as a commercialization vehicle:

- Easy to open and close;
- Focus on a single research theme and the resulting product;
- The high level of expertise of the team facilitates a flexible approach to the product and its adaptation to market trends;

- Ability to apply for funding for product development through start-up support programmes offered by external institutions;
- Simple business funding model;
- Ability to attract investors who are not interested in investing capital in universities. Spin-offs are easily supported by so-called business angels, in contrast to R&D work carried out directly by universities;
- Possibility to sell the company to an investor or another entrepreneur.

Disadvantages of the spin-off as a commercialization vehicle:

- The need to manage not only the ongoing project but also the company as a whole;
- The need to obtain funding;
- Difficulties in maintaining a positive cash flow;
- The need to meet public and legal obligations specific to the given business;
- When a spin-off company employs staff, it must comply with all employer obligations and labor law requirements, which constitutes an additional burden.

Running a spin-off company requires much more work and time than developing a new technology or product. Often, after setting up a spin-off company, researchers find that they are no longer able to devote themselves fully to their chosen research topic because running the company involves solving problems that they do not encounter in their work at the university or research centre.

In addition to day-to-day organisational matters, they have to keep the company's accounts in accordance with the accounting laws, prepare periodic financial statements, pay public and legal obligations such as social security contributions and taxes, monitor and service the market of suppliers, distributors and customers, manage production, carry out marketing, formulate a correct pricing policy, provide warranty and after-sales service.

The number and variety of management processes required depend on the size and nature of the business. The founding scientist of the spin-off, who is a specialist in their field, usually does not have sufficient management skills to carry out all these tasks alone. It is usually necessary to bring in several additional people with skills in different management areas. If these people are hired on the basis of an employment relationship, the management of the company has an additional, very important function - that of the employer.

As an employer, the academic spin-off must implement a human resources and payroll policy that complies with the regulations, e.g. pay salaries regularly, at the agreed time and in the agreed amount, along with taxes and social security contributions, if applicable, and ensure employees' rights. In addition to these activities, there is the process of fine-tuning the product and bringing it to market, as well as monitoring and responding to audience behaviour.

Note

Before setting up a spin-off company, the researcher should make a thorough analysis of all the pros and cons, to ensure the decision does become too much of a physical and emotional burden!

Business areas recommended for commercialization through a spin-off company:

- When there is a need to attract an investor to increase the technological readiness of a product, e.g. when companies providing funding for pre-implementation work require a start-up to be established with their participation, with the intention of selling their shares after a period when the technology has reached TRL 9;
- When applying for funding for an R&D project to further develop a product, e.g. when a business partner for implementation cannot be found;
- For niche activities where it is difficult to find a business partner with expertise;
- For products of common use that do not require sophisticated methods and tools to produce, so-called low investment products;
- When we offer a service that is very innovative but requires much more intellectual investment than fixed assets and real estate;
- When the service or product is aimed at a closed, defined audience;
- When the service has outsourcing characteristics.

Commercialization through a spin-off company is not recommended for sophisticated products and technologies:

- Significant financial outlay without the possibility of attracting an investor;
- Extensive infrastructure;
- Extensive human resources;
- Ownership of production lines;
- Audits and costly certifications.

In summary, spin-offs are small companies with up to 10 employees. They are mainly active in high technology areas such as pharmaceuticals, medicine, microbiology, chemistry and biotechnology. Most spin-offs are created in the United Kingdom, Finland and the United States. In Poland, spin-offs are most common in the IT, pharmaceutical and biotechnology sectors. These micro-enterprises are most often associated with academia but are also created by research and development institutions and private companies.

Relevant regulations in Greece

In Greece, the legal framework governing the establishment and operation of spin-offs, is primarily defined by **Law 4864/2021**. This law facilitates the commercial exploitation of research results by enabling researchers, universities, and research organizations to create spin-off companies.

Establishment Process and Institutional Framework of a Spin-off in Greece

1. **Application**
   Researchers submit an application for establishment of a spin-off to their university's Rector's Council or the Board of their research organization. This includes a draft contract outlining the relationship between the spin-off and the research organization, that has to be approved by the Council or other relevant body. The agreement should reflect the opinion of the respective Research Committee of the HEI, the Technology Transfer Office, or another competent body.

2. **Approval**
   The decision-making body has four months to approve the application. If they don't decide in time, the application is automatically approved. The research organisation, together with the co-researchers, must submit applications for the registration of intellectual property rights, if any, related to the results intended for exploitation by the spin-off, before the relevant decision on the establishment of the spin-off is made.

3. **Formation**
   Once approved, the spin-off must be officially established within six months. If not, a new application is needed.

4. **Joint Spin-Offs**
   Researchers from different organizations can create a joint spin-off. In this case, the request for establishment shall be submitted to the competent body of the organization to which the researcher belongs by drawing up a joint draft of a spin-off contract and shall specify the percentage of ownership of each research organization in the intellectual property rights assigned to the spin-off.

5. **Location**
   Spin-offs may have their registered office in Greece or another state, provided they establish a branch, office, or another type of establishment in Greece recognized as a permanent establishment under Greek tax legislation.

6. **Funding**
   Spin-offs may issue bonds or convertible bonds to meet their funding requirements. The research organization’s decision to approve the incorporation of the spin-off includes provisions for the transfer of IPR and the use of research equipment and infrastructure.

7. **Shareholders**
   Shareholders of the spin-off can include the researchers who developed the IP, the research organization, and external investors. The law also addresses potential conflicts of interest for researchers involved in spin-offs. Researchers can join spin-offs as founding partners, become partners after the spin-off is established, or take on roles as executive board members. They may also engage in research activities for the spin-off through project-based contracts.

Joint ventures with third parties, including both individuals and legal entities, are also allowed. Partners may join during the initial formation or later through share transfers or capital increases. For companies such as joint stock entities, shareholder agreements must define restrictions on share transfers, investor and partner rights during takeovers or dissolutions, and other essential governance matters.

8. **IPR**

   The law outlines the process for transferring intellectual property rights (IPR) from the research organization to the spin-off. This can include exclusive or non-exclusive licenses, or the transfer of IPR, with terms defined in an agreement between the research organization and the spin-off. If applications for industrial property rights are pending, they must be registered before the spin-off's approval. The spin-off contract plays a critical role in outlining the terms for licensing or transferring IP, financial obligations, and duties of good faith and transparency. For researchers who are both IPR holders and spin-off co-founders, the contract includes provisions for their dual role, detailing their obligations and rights in both capacities. The contract term is generally set at 10 years, unless otherwise agreed upon.

These regulations ensure that spin-offs in Greece promote innovation and commercialize research while protecting the interests of researchers and organizations.

Relevant regulations in Poland

In Poland, a university SPV is usually a single-member capital company established by the rector of a higher education institution with the consent of the senate for the purpose of indirect commercialization of the results of scientific activities or know-how related to these results, and whose sole owner is a higher education institution. The establishment of an SPV by public higher education institutions is a necessity in Poland, as a public entity such as a university is not allowed to acquire, take over or hold shares in spin-off companies.

The process of creating and acquiring spin-off companies by an SPV created by a research unit is in practice called **indirect commercialization**.

Definition

Indirect commercialization *- This means taking or acquiring shares in companies or subscription warrants entitling one to take or acquire shares in companies for the purpose of implementing or preparing to implement the results of scientific activities or know-how related to such results. In Poland, defined by the Act on Higher Education and Science of 20 July 2018.*

Relevant regulations in Romania

In Romania, the National Authority for Scientific Research and Innovation Decision no. 9685/2008 regarding the establishment and development of spin-offs by the research staff within the Research-Development Units (RDU) provides the way in which specialists within the research and development units establish spin-offs and the way in which the research and development units support the establishment and development of spin-offs.

Research-Development Units establish the criteria for granting support for the establishment of spin-offs by its own employees, and compiles a package of consulting services for the spin-off.

The object of activity of the spin-off must be correlated with the objectives of the RDU, to pursue the creation and marketing of products/technologies/services. Moreover, the products (or technologies or services) created must be based on the know-how and results of research carried out within the RDU.
The initiators of the spin-off must have both, the technological knowledge and entrepreneurial skills to manage it.

The creation of a spin-off must be approved by the RDU board of directors, which must agree with the act of establishment of the spin-off company, the business plan, the value of the knowledge and research results, the volume of the financial contribution, the contract regarding the use of the RDU infrastructure by the spin-off.

RDU can be an associated partner in the spin-off based on an association/partnership contract drawn up in accordance with the legislation in force on commercial companies, which

establishes, by mutual agreement, the percentage participation in the exploitation of intellectual property rights as well as the rights to publish and disseminate the results obtained.

If the research activity leads to the obtaining of a patent, a clause for the distribution of expenses, income or intellectual property rights is established by contract.
The spin-off periodically presents an activity report and a plan to the members. Annually, the RDU management evaluates its participation in the spin-off.

3.3.2. Spin-out company

Unlike a spin-off, a **spin-out** is organisationally and financially independent of the parent organisation. The company is an entity created by one or more employees of the parent organisation using its intellectual resources on the basis of a separate contract.

In the literature discussing the concepts of spin-offs and spin-outs, it is possible to find a situation where these definitions are often used interchangeably as synonyms or the exact opposite. This is likely due to the fact that both are companies whose purpose is to exploit the intellectual property of the parent organisation.

In summary, the choice of the most appropriate form of spin-off depends on the degree of dependence that the founder-creator wishes to have on the parent organisation. However, it is clear that both types of companies can be used successfully to commercialise research and scientific and development work.

3.4. Creator's remuneration

If the rights to research outputs do not belong to the authors or inventors and are commercialized by another entity, such as an employer or commissioner, the authors may still be entitled to additional remuneration. This possibility is regulated by national laws and may be contingent on the success of the commercialization. The default rules regarding the remuneration of inventors or authors are determined by national law. Some of these default provisions can be modified through contractual agreements. However, each national legal system may include mandatory provisions (*ius cogens*) that cannot be altered or overridden by the contracting parties.

Relevant regulations in Greece

According to Inventions law (Law 1733/1987)

- **Service Inventions**: For inventions created under a contractual obligation for inventive activity, the rights belong entirely to the employer. If the invention becomes particularly profitable, the creator has the right to request reasonable additional compensation. The amount is typically negotiated based on the invention's profitability and the terms of the employment contract.

- **Employment inventions**: If an invention made during employment becomes particularly profitable, the creator can request additional compensation, which is negotiated based on the invention's success and the employment contract. While extra payment for commercialization isn't typically required for works created during employment, specific contracts might include clauses for additional remuneration if the work is commercially successful.

Relevant regulations in Poland

According to the Law on Higher Education, creators are entitled to a share of the benefits arising from the commercialization of results generated by them.

The Law on Higher Education and Science establishes a minimum share of the benefits derived from commercialization that must be paid to creators who are employees of public universities. The regulation regarding creators' remuneration applies when the commercialized results fall within the defined catalogue, which includes:

- Results of scientific research, such as inventions, utility models, industrial designs, integrated circuit topographies, or bred, discovered, and derived plant varieties.
- Results of development work or artistic creativity.

- Know-how related to these results.

In case of direct commercialization:
Creators are entitled to at least 50% of the benefits obtained by the university from direct commercialization. This amount can be reduced by a maximum of 25% to cover costs directly incurred by the university or its SPV related to this commercialization.

In case of indirect commercialization:
Creators are entitled to at least 50% of the benefits obtained by the SPV from indirect commercialization. Similarly, this amount may be reduced by up to 25% to cover costs directly incurred by the university or the SPV related to this commercialization.

In both cases the university is obliged to pay the respective remuneration to the employee. A particular situation arises when an employee of a public university pursues the commercialization of their own invention within a spin-off company. In that case, the employee is nevertheless entitled to additional remuneration.

Copyright Law
Polish Copyright Law includes special provisions on remuneration for commercialized works. These provisions apply, for example, in cases involving the sale of the original work or when the author's remuneration is disproportionately low compared to the benefits derived by the assignee or licensee from the commercialization of the work.

Industrial Property Law
If the inventor creates an invention, utility model, or design:

- Under an employment contract,
- Under a commission contract,
- With the assistance of an enterprise,

or if the inventor transfers the rights to the invention, utility model, or design to the enterprise, or authorizes the enterprise to use it, the inventor is entitled to remuneration from the enterprise in the event of the use of these results. The remuneration may be determined by mutual agreement between the parties. If no such agreement is reached, the remuneration

should be in a justified proportion to the benefits obtained by the enterprise from the implementation of the result, while taking into account other relevant circumstances. The parties may also agree that the inventor will not receive remuneration.

If the remuneration has not been agreed upon by the parties but has been calculated based on the benefits obtained by the enterprise, the inventor's remuneration should be increased if the benefits derived by the enterprise significantly exceed those initially used for the calculation.

Relevant regulations in Romania

In Romania, inventors are entitled to remuneration for their inventions, especially when they are employed by a company, research institution, or any other legal entity. The general framework for this is established under the Romanian Intellectual Property Law, specifically Law No. 83/2014 regarding the rights to inventions and the Romanian Labor Code. The specific remuneration depends on various factors, such as whether the invention is created within the scope of the inventor's employment or whether it’s an independent creation.

Here are the key points related to inventors' remuneration in Romania:

- For service inventions which have been obtained, during the individual employment contract, and for a maximum period of 2 years from its termination, as the case may be, by knowing or using the experience of the employer by using the material means of the employer, as a result of the training and training acquired by the inventor employed by the care and at the expense of the employer or by the use of information resulting from the work of the employer or made available by him, which have been claimed by the employer, the employee inventor is entitled to a remuneration set by the employer.

- As regards the criteria for determining remuneration, the employer shall define them by specific provisions of the internal regulation. In the absence of specific provisions, the employer shall consider, depending on each specific case, one or more of the following criteria:

- the economic, commercial and/or social effects arising from the exploitation of the invention by the employer or by third parties with the consent of the employer;
- the extent to which the employer is involved in the making of the service invention, including the resources made available by the employer to carry it out;
- the creative contribution of the wage-earner, when the invention was created by several inventors.

3.5. Support for Polish Startups: Financial, Organizational, and Mentoring Opportunities in Poland

Poland's startup ecosystem continues to mature rapidly, backed by a coordinated network of public institutions and targeted EU-funded initiatives under the European Funds for a Modern Economy (FENG). The Polish Agency for Enterprise Development (PARP) serves as the central hub for most practical support aimed at innovative early-stage companies, while the National Centre for Research and Development (NCBR) and the Foundation for Polish Science (FNP) focus on research-driven innovation and commercialization. The National Science Centre (NCN) and the Ministry of Science and Higher Education play more indirect roles, primarily enabling academic spin-offs and broader policy frameworks. Non-governmental actors—university accelerators, corporate programs, and foundations—complement these efforts with flexible, sector-specific offerings.

The following overview addresses three core questions, based on information from current official sources.

1. Specific Financial Instruments Available and How to Access Them

The dominant instrument is **non-repayable grants** delivered through structured acceleration programs. PARP's flagship **Startup Booster Poland – Smart UP** offers up to **400,000 PLN per startup** (100% of eligible costs, no own contribution required). Eligible expenses include employee salaries (including civil-law contracts), external services for milestones, fixed and intangible assets, and promotional activities. A dedicated "Poland Prize" pathway adds concierge-style "soft-landing" services for foreign founders.

Access is primarily accelerator-led, rather than managed through a central PARP portal:

- Startups apply directly to one of the 16+ approved operators (e.g., Huge Thing, Accelpoint, SWPS University, Krakowski Park Technologiczny, Startup Hub Poland).
- Each operator runs its own recruitment rounds with tailored paths: industry-specific B2B/B2A matching, investor-focused (VC), sector-agnostic market validation, or "Go Global" international scaling.
- Program applications remain open until April 2026. Several operators continue to accept submissions. Full details and application links are available on the operators' sub-pages at feng.parp.gov, e.g., the Small Grants Scheme for female-led enterprises, combining innovation services with mentoring and investments) and legacy acceleration schemes that have largely folded into Smart UP.

NCBR complements this with **R&D project grants** under FENG (often in partnership with PARP) and operates the NCBR Investment Fund for equity-style co-investments in growth-stage innovative SMEs. Eligibility typically requires a deep tech research or technological component; applications follow standard NCBR calls published on ncbr.gov.pl.

FNP's **PRIME** (Program for Research Innovation and Market Excellence) and **Proof of Concept (PoC FENG)** provide early commercialization grants for academic teams. Amounts vary by call but focus on market-validation costs; applications open periodically on fnp.org.pl (e.g., FIRST TEAM FENG call planned for Q1 2026).

The Ministry of Science and Higher Education channels funding into specialized initiatives such as the Stanford SPARK Poland biomedicine program, which includes project grants alongside mentoring.

Non-governmental sources provide equity or hybrid instruments, such as university seed funds, corporate accelerators like Orange Fab Poland, and private VC networks linked to PFR Ventures. However, public grants remain the most accessible entry point for most founders.

2. Eligibility Criteria for Governmental and Non-Governmental Support

PARP programs (Startup Booster / Poland Prize) target **micro or small enterprises** (per EU Regulation 651/2014) that:

- Operate for no longer than five years from first registration,
- Are innovative (technological product or service with market potential),
- Are not listed on a stock exchange.

Foreign founders are explicitly encouraged to apply through the Poland Prize program and are required to incorporate in Poland upon selection. Women-led ventures benefit from dedicated streams with relaxed contribution requirements.

NCBR R&D grants and investment fund support require a Polish-registered company (or R&D center) with a credible research component; consortia with universities are encouraged.

FNP PRIME and **PoC FENG** are open to **scientists and research teams** employed by Polish research organizations forming spin-off or commercialization projects. Academic credentials and a clear path to market are decisive.

NCN grants (OPUS, PRELUDIUM, etc.) remain almost exclusively for basic research conducted by academic entities; commercial companies participate only as minor partners or R&D centers, so they are rarely suitable for pure startups.

Non-governmental programs, including university incubators, corporate accelerators, and foundations such as Startup Poland, generally mirror the criteria above but offer greater flexibility. For example, they may not enforce a strict five-year rule or may focus on specific sectors such as artificial intelligence, cleantech, health, or social impact.
All schemes require a business plan or acceleration proposal, Polish tax residency or incorporation, and adherence to state-aid rules. Applications are competitive; selection occurs via accelerator panels or expert committees.

3. Mentoring Programs Approach and Effectiveness Across Development Stages

Mentoring is a centerpoint of nearly every public program and is deliberately adjusted to startup maturity.

At the early or pre-seed stage (idea validation and MVP development), PARP accelerator paths and FNP PRIME provide intensive, milestone-driven mentoring. This includes weekly sessions with industry experts, investor pitch training, and corporate matchmaking. The approach is highly structured and hands-on, with operators assigning dedicated mentors to refine value propositions, test assumptions, and build initial teams. Foreign founders participating through Poland Prize receive additional concierge support for legal setup and local networking. This model is highly effective for rapid learning and risk reduction; many founders report achieving faster pivots and acquiring first customers within the 3 to 6 month acceleration period.

At the seed or growth stage (scaling, market entry, and international expansion), programs emphasize strategic mentoring. This includes investor relations, Go Global preparation for target markets such as Germany, the USA, and Asia, and the development of B2B or B2A partnerships. Operators such as Huge Thing and Concordia Design facilitate connections between startups, corporate technology seekers, and venture capital funds. The mentoring style becomes less prescriptive and more advisory, focusing on negotiation skills, cap-table management, and regulatory compliance. Effectiveness is enhanced when combined with financial grants, as startups frequently secure follow-on private capital or pilot contracts. Reports from the ecosystem indicate that public mentoring at this stage is particularly effective in facilitating connections with large Polish and European corporations.

At the academic spin-off stage (research commercialization), FNP PRIME and Ministry-backed programs such as SPARK Poland focus on scientist-oriented mentoring. This includes intellectual property strategy, market validation workshops, and commercialization training modeled after Oxentia's approach in the United Kingdom. The mentoring approach is collaborative and cross-disciplinary, pairing researchers with business mentors. This model is particularly effective for deep-tech teams that face challenges in bridging the research-to-market gap, resulting in the faster creation of viable spin-offs compared to traditional academic pathways.

Non-governmental mentoring, including university peer networks, corporate programs such as Orange Fab, and independent platforms, tends to be more flexible and longer-term. These arrangements are often unpaid or involve minimal equity and rely heavily on personal rapport. Founders at later stages frequently combine public acceleration programs with private mentors to ensure sustained support.

Across all development stages, public programs are distinguished by their scale and integration of funding with mentoring, whereas private or university schemes provide more tailored support. Success rates increase significantly when mentoring is aligned with the startup's specific stage of maturity. Early-stage teams benefit most from structured and rapid support, while growth-stage teams gain from strategic networks and international exposure.

Practical Next Steps for Founders

1. Prospective founders should visit feng.parp.gov.pl to review the current list of Startup Booster operators and select those whose sector focus and Go Global destinations align with their business objectives.
2. Applicants are advised to prepare a concise pitch deck and register on the selected accelerator's portal.
3. For research-based projects, applicants should consult fnp.org.pl for open PRIME or PoC calls and ncbr.gov.pl for available R&D grants.

4. International founders are encouraged to explore the Poland Prize pathway, which offers the most expedited soft-landing support.

Poland's support landscape is generous, competitive, and notably founder-friendly, particularly for those prepared to act swiftly. The combination of non-dilutive grants, expert mentoring, and corporate matchmaking provides ambitious teams with a substantial runway for scaling, whether developing a fintech enterprise or a deep-tech spin-off from a Polish research institution.

Part 4: S2B partnership

4.1 SWOT analysis of the project result

To effectively implement the project results, we must look at them as a product that is intended to respond to a specific market need and compete in the existing marketplace. One of the universal tools that allows you to assess the market potential of a product is SWOT Analysis.

Understanding the components of a SWOT Matrix

SWOT Analysis, a strategic planning model, evaluates an organization's Strengths, Weaknesses, Opportunities, and Threats. It provides essential insights into project viability and potential success. In the context of Science-to-Business (S2B) project management, SWOT Analysis helps identify internal and external factors affecting project outcomes. By conducting a SWOT analysis we can determine the conditions for introducing the result of the research project to the market and assess the chances of success.

The analysis consists of four elements: two internal ones regarding the project result itself and two external ones regarding the environment in which the result will be commercialized.

- Internal Analysis: Strengths and Weaknesses **Strengths:** These include all the project's advantageous characteristics, that distinguish it from similar initiatives, for example, having an experienced project team or offering a high-quality product/service.
- **Weaknesses:** These are characteristics that may place the project at a competitive disadvantage, such as insufficient financial resources or inadequate management skills.

We shall analyze the external environment in terms of opportunities and threats.

- **Opportunities:** These are favorable conditions or external factors that could benefit the project. For instance, a growing demand for a product or service offered by the project.
- **Threats:** These are external situations or conditions external to the project that could negatively impact the project's success. Examples include economic fluctuations or technological advancements.

https://en.wikipedia.org/wiki/SWOT_analysis

Steps to Conducting a SWOT Analysis:

- **Assemble a Team**: Conducting a SWOT analysis is most effective when done collaboratively. Gather a diverse group of stakeholders to brainstorm and the various factors affecting the project.

- **Utilize Project Management Tools**: Leverage project management software to enhance team communication and collaboration, particularly in remote or hybrid work environments.

- **Explore Internal and External Factors:** Identify and analyze both internal and external factors affecting the project.

- **Document the Results:** Writing down the findings helps clarify ideas and makes it easier to share insights with team members.

- **Reassess Periodically:** Throughout the project's lifecycle, conduct regular re-evaluations (e.g., every six months) to note any changes. This practice allows for timely adjustments to your commercialization strategy.

Interpretation of SWOT Analysis results

SWOT analysis helps focus on project strengths, minimize risks and identify project gaps, enabling proactive strategy planning.
However, interpreting the results can present challenges. For instance, addressing uncertain or ambiguous factors and prioritizing issues may lead to a lengthy and disorganized list of elements.
To avoid confusion in interpreting the SWOT analysis results, categorize the identified factors based on their impact on the commercialization of the project. Concentrate on those elements that will have the greatest impact on the success of the project.

How to use the result of SWOT in further planning the marketing strategy

- Building on Strengths: Identify and reinforce strengths of your product
- Addressing Weaknesses: Acknowledge your product's weaknesses and seek ways for improvement.
- Seizing Opportunities: Capitalize on favorable conditions in the business environment and on the market
- Mitigating Threats: Anticipate and counteract potential external threats.

Remember that your product must possess strong advantages to compete effectively in the market. While it's important to recognize weaknesses, the primary focus should be on enhancing strengths.

The insights gained from the SWOT analysis will deepen your understanding of your product and the environment in which you will commercialize it, aiding in the search for partners to implement your idea.

Example: SWOT analysis of Electric Vehicles

Strengths:	**Weaknesses:**
• Latest technology, still under development • High energy efficiency • Low running costs • Total power available regardless of engine speed • High ride comfort • Low noise • Zero emissions	• Higher production costs compared to internal combustion engines • Limited range on a single charge • Long charging time • Limited battery life • Lack of noise while driving poses a danger to pedestrians
Opportunities:	**Threats:**
• Tax relief on purchase • Electric mobility subsidies • Possibility to use bus lanes • Product under development, constantly improving: longer range, faster charging • Expansion of charging infrastructure provides opportunity to reach new customer segments • Growing environmental awareness • Rising fuel prices driving demand	• Many types of chargers • Lack of charging points • Lack of co-operation between manufacturers • Dependence on battery power • Uncertain price and availability of raw materials • Uncertainty of operational safety

As illustrated some strengths can also be perceived as weaknesses . For example, the lack of noise of electric vehicles is a comfort for the driver but poses a risk to pedestrians. To mitigate this, electric cars are equipped with a system that generates engine noise to avoid accidents with pedestrians.

Threats can also be turned into opportunities; the lack of charging points is a challenge, but the ongoing development of charging infrastructure in many countries is an opportunity to increase sales in the future.

4.2 Commercialization strategies with business partners

4.2.1. Identifying Potential Partners

The implementation of the result of research and development results from a university must take place in collaboration with an industrial partner. Universities and research institutes typically lack the resources and infrastructure to scale up and produce commercial products. In a partnership, universities and research institutes act as the system provider - originating the idea, while the industrial partner, often a production facility, serves as the system user, responsible for bringing the project results to fruition.

Note:

Members of the research team must be aware that no implementation will take place in the laboratory and that the participation of an industrial partner in the process is essential!

The project plan must include space, tasks and the associated budget for the industrial partner. This partner need not be the final recipient of the project result. In most cases, they often serve as the intermediary between the technology provider and the end user, assuming responsibilities related to production, product certification, marketing and distribution. These are tasks that cannot be performed by the research team due to a lack of physical capacity but are necessary to bring the product to market. Potential commercialization partners should be companies within the relevant industry that possess the necessary financial resources and infrastructure. It is vital that these partners have a solid understanding of the industry and the needs of the target audience.

The industry serves as an excellent barometer for assessing the market value of innovations, as. companies have an intimate knowledge of end-user requirements, as the products and services they bring to market must be competitive. Additionally, industry players to minimize the risks associated with a new product or market segment.

Meetings with potential partners should be targeted at segments of the industry where we have innovation to offer, where we feel confident and where we have the ability to conduct in-depth research into a new product.

Business discussions should be concise and focused; companies typically have a need for innovation, and while they may possess the necessary infrastructure, they often lack ideas. In meetings, it is important to present ideas clearly and succinctly, avoiding the disclosure confidential information in the early stages of discussions.

The innovator should stay informed about developments in their industry and reach out to multiple companies when seeking implementation partners. They should meet regularly with representatives of the companies can provide valuable insights into their plans and needs.

Types of Business Partnerships used in s2b cooperation

The main objective of an S2B partnership is to streamline production processes, improve product functionality or implement new solutions, so it is important to define the partnership model appropriately to achieve the objective as effectively as possible.

The following cooperation models are the most common:

- **Strategic Alliances**

  Businesses with complementary skills or resources team up to pursue a common goal. This model often involves knowledge sharing and technology transfer.

- **Joint Ventures**

  Two or more companies create a separate entity to achieve a specific goal, such as entering a new market or developing a new product. All partners share risks and rewards.

- **Licensing**

  A business grants another the right to use its intellectual property in exchange for royalties. This model is common in industries like technology and entertainment.

<u>Examples:</u>

1. A computer program to help manage an industrial plant in real time, based on continuous measurements of technological parameters. In principle, once such a

product has been tested and the data from the specific equipment (obtained from the end user) has been fed into the algorithms, it does not need to be scaled up and can be sold as a ready-to-use product.
However, deploying such software requires appropriate hardware, operational knowledge and the tools and skills to maintain, update and troubleshoot the software. Therefore, the optimal business partner for the implementation of such software will not be the end user - the owner of the plant/algorithmic production line, as his competence relates to the product coming off the line.

The plant owner needs to use the services of a company that provides the software, guarantees its correct functioning and provides full after-sales support. Such a service cannot be provided by the university where the software was developed. The implementing partner will therefore be an IT company that can offer the software on the basis of purchasing a license from the university, or even purchasing the right to use the software without time, application or territorial restrictions.

This company can benefit from the university's technical support in the event of problems with the software or the need to adapt further functions, but the end-user (production line) support itself will not be a burden on the university's staff wishing to carry out new research.

Note:

The business partner is the bridge between the system provider and the system user.

2. Another example of an S2B partnership is a joint application for an externally funded research and deployment project. Here, the type of relationship between the university and the company is usually determined by the conditions of the competition. In most cases it is a consortium partnership, i.e. all partners are jointly and severally liable for the results of the project, which is treated as a joint venture.

In some competitions, the partnership involves the university commissioning research work to develop an innovation by a company, which then implements this innovation in its business practice.

4.2.2 Matters needing attention in commercial partnerships

1. **Clear Objectives**

Partners must define and align their goals and expectations before entering the partnership. This ensures that both parties are working towards the same outcomes.

2. **Mutual Benefit**

A successful partnership should result in mutual benefits for all parties involved. Imbalances in benefits can lead to conflicts and the eventual breakdown of the partnership.

3. **Trust and Transparency**

Open communication and transparency are crucial. Partners should share information and insights to build trust and ensure that everyone is on the same page.

4. **Legal Agreements**

Draft legally binding agreements that outline each partner's responsibilities, contributions, profit-sharing arrangements, dispute resolution mechanisms, and exit strategies.

5. **Resource Commitment**

Partners must commit the necessary resources, including time, capital, and expertise, to the partnership's success.

6. **Risk Management**

Identify potential risks and develop strategies to mitigate them. This could involve contingency plans for unforeseen challenges.

7. **Regular Evaluation**

Regularly assess the partnership's performance against set objectives. Adjustments can be made as needed to ensure alignment with changing market conditions.

Contractual Agreements: Drafting and finalizing contractual agreements with business partners

After negotiating the terms and conditions of the partnership, the next step is to draft and review the partnership agreement or contract. It is essential to ensure that the document is clear, concise, accurate, and comprehensive, reflecting the mutual understanding and agreement of both parties. Consulting with legal and financial advisors is crucial to ensure the document complies with relevant laws and regulations. Careful review is necessary to identify any errors or inconsistencies, and to request clarifications or revisions if needed. Once both parties are satisfied with the document, the partnership agreement or contract is signed and finalized, following proper procedures and formalities. This may involve using electronic signatures, witnesses, or notaries. Keeping a copy of the document for records and sharing it with relevant stakeholders marks the official start of the partnership and the beginning of the implementation phase.

Launch and manage the partnership

Effective communication and collaboration with your partner are paramount at this stage. Execution of the partnership plan should adhere to the agreed deliverables, milestones, and metrics. It is crucial to monitor and measure the performance and results of the partnership continually. Providing feedback and support to your partner is essential for the partnership's success. Celebrating successes, addressing challenges, and resolving any arising issues or conflicts are vital tasks. Regular review and evaluation of the partnership should be conducted to identify areas for improvement and growth.

How the industry can help the scientist?

Industrial activity is an excellent market barometer. The application value of the invention shall be not based on intuitions, but on facts. Industry has experience as a given product or service sells itself on the market. Very often the perception of the demand for a given product feature by a scientist and entrepreneur differs dramatically; thus the entrepreneur knows how to target the product so that it can be sold. Moreover, the industry helps to define the risks associated with an innovative project.

How the scientist can help the industry?

For the company, that lack well-equipped laboratories and high qualified team of research teams, universities serve as their R&D centers, assisting in the development and testing of inventions before the scaling process. Strategic partnerships in applying for joint R&D projects can also provide the financial resources to conduct the research.

For companies with their own R&D center and staff, universities can furnish auxiliary expertise in specific issues, being the objective for long term university research programs that companies may not have the time or access to pursue.

Note:

The mutual benefits of S2B partnerships are the basis for success!

What the industry expects from scientists?

Businesses place a high value on time; **time is money.** The industry focuses on rapid product sales, while scientists often engage in lengthy and detailed work on inventions.

The industry expects scientists to align with market recommendations regarding product orientation. They also anticipate that scientists will be ready to collaborate on implementation and demonstrate determination in their efforts.

Moreover, the industry is generally **risk-averse**. They expect cooperating scientists to actively work on minimizing the risks associated with introducing innovations to the market.

What elements of the research project make it attractive for the entrepreneur?:

- The invention is in line with current needs signaled by users
- The invention gives the opportunity to gain a competitive advantage by the entrepreneur
- The project is at the stage of development enabling pre-implementation and implementation work
- The project is well-defined and intelligibly described
- The project is correctly conducted, with a clear schedule and marked milestones
- The project is regularly consulted with the implementing company and adapting to potential changes in requirements

What barriers of cooperation between industry and science can be seen by entrepreneurs?:

- Lack of scientists' confidence in the industry and vice versa;
- Sometimes, scientists speak disparagingly of industry, considering the pursuit of profit as questionable;
- Researchers are too attached to their ideas to bend to market requirements;
- The scientific projects are often on significantly low market readiness and scientist is not willing to develop it;
- The time between capital investment on the development of the invention and its market implementation is crucial;
- Pre-implementation and implementation work must be faster than the changes in market demand for a given product feature.

4.2.3 University broker's role in S2B interaction

A technology broker (innovation broker) is a specialization that has emerged in the last decade as a result of the global development strategy's focus on bringing innovative solutions to the market.

In practice, the broker has to combine knowledge and experience from various fields. They should understand the specifics of research work, be familiar with the principles of market operation, and have technical, economic, legal and sociological knowledge. Strong communication and negotiation skills are also important in the broker's role.

- The broker works on the development of the invention together with a scientist
- The broker acts as an intermediary and interpreter between the scientist and the industry
- Through contact with many entrepreneurs, the broker finds industry partners to recognize the sought after product features
- The broker "translates" the content of the invention from scientific language to the language of the market
- They consult potential applications with current market demand

When and how to introduce market factors to the research project?

Introducing market elements to the project should begin the moment when the idea for the invention arises in the scientist's mind. As the definition of the invention's features progresses, it should be accompanied by an improvement in the needs it aims to satisfy. The creator shapes the product's characteristics based on their identification of the specific needs that the product must address.

The commercialization strategy for the invention should be established at the initial stage of the project and adapted to the evolving characteristics of the invention or market conditions

If during the project development, which extends beyond the conceptual phase, it becomes impossible outline of the commercialization strategy, it is likely that the project will not be suitable for implementation

How to effectively search for business partners?

Usually, every company has the need for innovations. The scientist and broker must stay updated on the news in the industry in which they operate. The broker should reach out to multiple companies, meet their representatives and discuss their development plans

Meetings should be focused on the segments where we have inventions to offer, as companies prefer not to waste time discussing irrelevant topics. It is advisable to invite scientists to such meetings to present their invention – clearly and concisely.

Never send a patent description to the company!

When it is more profitable to establish cooperation with a small business and when with a large one?

Some inventions are better suited for development in the start-up, others require established companies firmly embedded in the industry. The decision on which development strategy to implement is always unique and requires thorough analysis. A small entrepreneur can be an excellent partner for projects implemented on local markets. This is particularly true when introducing innovations does not require an extensive marketing campaign and when the sale of a product or service does not necessitate distribution channels

A large enterprise should be chosen as a partner for inventions entering large-volume production, where it is necessary to have a technological line, warehouses and logistics

A large enterprise is also a suitable partner for highly innovative solutions requiring high expenditure on implementation. However, large companies typically require that innovations

align perfectly with their development strategy. In general, large companies do not invest in technologies or products with poorly defined scopeσ of application and/or that do not meet market targets.

When to look for cooperation on the domestic market and when on an international scale?

Local Market:

- Products and technologies having several substitutes;
- Regional usage of product;
- Lack of recognized international competition;
- Domestic Intellectual Property protection only.

International Market:

- International protection of Intellectual Property Products and technologies with unique features that are difficult to replicate Main production and distribution chains located abroad;
- Implementation strategies focus on other markets.

Long term S2B relationship

- Maintain contact with company representatives;
- Stay informed about organizational changes within the company;
- Follow the strategic development of your partners;
- Inform them when new opportunities arise at the university Invite them to the seminars organized by the university, local authorities etc.;
- Ensure that the meetings and conferences you invite them to offer valuable insights for the industrial partner;
- Receive regular feedback from your partner and work on influencing the scientists.

4.3 Valuation of intellectual property

The result of a research and development project is intellectual property (IP), which has an economic value. IP valuation is the process of determining the monetary value of these assets. It is critical for transactions that involve sharing IP with another party, such as licensing, selling or entering into collaboration agreements. Understanding the value of intellectual property (IP) assets is essential for all parties involved in the process.

The value of IP depends on many factors and changes over time. The main factors affecting the market value of the result are:

- Degree of market maturity. The value of the IP increases as the marketability of the result increases. (TRL level of readiness for implementation)
- Market potential. The higher the market potential of an outcome, the higher its value.
- Novelty. The value decreases with the time between the development of the outcome and its implementation. It may be that the intellectual property has no value after a few or several years.
- Uniqueness. Weak and limited competition increases the value of the result.
- Accessibility. Limiting accessibility through patent protection increases the value of the result.

Methods for valuing IP assets:

1. **Cost method**

The cost method establishes the value of an IP asset by calculating the cost of a similar or exact IP asset. This method is useful when the IP asset can be easily reproduced, and when the economic benefits of the asset cannot be accurately quantified. Cost method is most commonly used to calculate the minimum price what the university shall obtain as a reward by selling rights to the project outcome, because it assumes that the price set is to reimburse the costs incurred by the research entity in developing the result.

2. **Market method**

The market method values IP assets by comparing them with similar assets for which actual prices have been paid under comparable circumstances. This method is straightforward and based on market information, making it useful for establishing approximate values for determining royalty rates, tax, and inputs for the income method.

3. **Income method**

The income method is the most commonly used method for IP valuation, however is not the most accurate to valuation of result of R&D projects. It values the IP asset based on the economic income it is expected to generate, adjusted to its present-day value. This method is suitable for IP assets with positive cash flows, whose future cash flows can be estimated reliably, and for which a proxy for risk can be used to obtain discount rates.

4. **IP valuation by DCF method**

- **Conducting an IP audit**

By conducting an IP audit, businesses can ensure that their IP assets are properly valued and protected, making them more attractive for potential partnerships, investments, or other transactions. This process includes:

  - Identifying and cataloging IP assets
  - Reviewing legal documentation
  - Assessing the strength and enforceability of IP rights
  - Evaluating the competitive landscape
  - Identifying any potential infringement risks

The Discounted Cash Flow (DCF) method is a popular valuation technique used to estimate the value of an investment based on its expected future cash flows

- **Key concepts**

Discounted cash flow (DCF) analysis estimates the present value of expected future cash flows using a discount rate. It helps determine whether an investment opportunity is worthwhile by comparing the DCF value with the current cost of the investment.

- **Projecting Cash Flow**

To conduct a DCF analysis, investors must estimate the future cash flows of the investment, equipment, or other assets. These cash flows are then discounted back to the present day using a projected discount rate.

- **Determination of Remaining Economic or Useful Life (RUL) of the IP asset**

The time value of money assumes that a dollar received today is worth more than a dollar received in the future because it can be invested. Hence, DCF analysis is used to estimate the money an investor would receive from an investment, adjusted for the time value of money.

- **Risk Consideration and Discount Rate determination**

The discount rate used in DCF analysis is crucial and varies depending on the project or investment under consideration. Factors such as the company's risk profile and the conditions of the capital markets affect the discount rate chosen. If the investor cannot estimate future cash flows accurately or the project is complex, DCF may not be the best valuation method.

Example of DCF

Your company wants to launch a project with a weighted average cost of capital of 5%.

The initial investment is $11 million, and the project will last for five years, with the following estimated cash flows per year:

Year	Cash Flow
1	1 M
2	2 M
3	3 M
4	4 M
5	5 M

Using the DCF formula, the calculated discounted cash flows for the project are determined, and the net present value (NPV) is calculated. If the NPV is positive, the project may generate a return higher than the initial cost and could be considered worthwhile.

Advantages and Disadvantages of DCF:

Advantages:	Disadvantages:
• DCF analysis provides an idea of whether a proposed investment is worthwhile. • It can be applied to a variety of investments and capital projects.	• DCF relies on estimates, not actual figures, and the result is also an estimate.

• Projections can be tweaked to provide different results for various scenarios, allowing users to account for different projections.	• Future cash flows rely on various factors that cannot be quantified exactly, such as market demand, economic conditions, and competition. • DCF should not be relied on exclusively, and other valuation methods and known factors should be considered.

How Do You Calculate DCF?

Calculating DCF involves three basic steps:

1. Forecast the expected cash flows from the investment.
2. Select a discount rate, typically based on the cost of financing the investment or the opportunity cost presented by alternative investments.
3. Discount the forecasted cash flows back to the present day.

Practical usage of calculated value of IP

It is best to evaluate the project results using two separate methods and compare the outcomes. If the results are inconsistent, it likely indicates that incorrect assumptions were made. Verify your assumptions and perform the calculations again.

The calculated price should be included in the offer we make to the potential recipient. In the offer, we propose a price slightly higher than the calculated one, leaving a margin for negotiations.

The general rule is that IP shall not be sold below its cost value, in order to reimburse the expenses incurred in developing the product. Sales price shall be the market price. It means that the actual IP value is as much as the buyer is willing to pay for it. With many potential buyers, the value of the IP may increase. This value is always negotiated with the potential buyer and the right to the result should be sold to the highest bidder.

4.4 Constructing a technological offer

A technological offer is a structured proposal that outlines the main features of project result and its advantages. The proposal is the document that initiates the process of negotiation with potential investors/manufacturers/users.

The offer may be intended for inclusion:

- on the website
- in the conference directory
- as so-called White Paper for the professional seminar
- to be sent to a potential investor

The proposal should vary according to its final destination. The first three types of offers are general information about the technology, a brief description of the technology or invention in non-technical language, listing the functions to be achieved, possible areas of application of the technology/product.

An offer to a specific investor should be much more thoughtful and provide details without revealing the essence of the solution. It is essential to issue a proposal before signing a confidentiality agreement.

In this type of proposal we shall include following:

1. **Administrative and legal information**

The offer includes administrative and legal information for a potential investor

- The entity submitting the proposal (University, TTC)
- Name and title of the scientist, author of the invention
- The department, institute in which they work

2. **Subject of the proposal**

- Brief description of the technology or invention in non-technical language
- A scientific hypothesis and a rational basis for research in the direction of this technology / product
- The function to be achieved possible fields of application for the technology / product

3. **Principle of operation**

- A simplified description of the principle of operation

Note:

This description should not contain any confidential or protected information, even if the patent is granted, and cannot be a description of a patent application!

4. **The Goal of invention**

- The main focus in preparing the proposal is to clearly inform what this technology/product can do, but not how it is made.

5. **Verification indicators**

- The main indicator that the technology / product fulfills its function
- Data confirming the effectiveness of the product technology
- Test results - preferably based on applicable standards
- Other indicators proposed by the scientist
- Coefficients should be quantitative and qualitative

6. **Market information**

- The state of the art
- current competitive products / substitutes used in the market
- Brief description of the competition

7. **Advantages given by technology/product**

- Unique features that contribute to sale success: the so-called "WOW" factor
- comparison to currently used products
- If we make the proposal is for specific company, we could refer to this company's actual products

8. **TRL level of invention**

In the case of a technology / product that is not ready for sale, and we are looking for a partner for the B & R project for pre-implementation work, we must provide:

- TRL readiness level with justification

- What work / actions should be taken to prepare the technology / product for implementation on the market and sale process

9. Optional: action plan for market implementation

In the case of a technology / product at a very low TRL level, there is a high probability that we will not be able to describe all 10 features, because we simply do not have the knowledge yet, e.g. data confirming effectiveness.

In this case, these issues should be listed in the action plan.

10. Intellectual Property Rights

We should inform the party receiving the proposal about who holds the actual Property Rights and who will negotiate on behalf of the university

11. Proposed price

- The price for the purchase of the rights to the patent or license
- An Invitation to negotiate
- an invitation to conduct joint research on the technology/product
- Details of the person for further contact

12. Proposal validity Period

The Proposal should be valid for at least one month but no longer than 6 months from the date of submission. After this period, the proposal may need to be renewed, and the price recalculated.

4.5 Negotiations

Negotiating a successful Science-to-Business (S2B) partnership agreement requires careful planning and consideration.

Understanding the Value Proposition

Before entering into negotiations, having a clear idea of what can be offered to the potential partner and what can be expected from them in return is crucial. The value proposition should be based on strengths, capabilities, and competitive advantages, as well as the partner's goals, challenges, and preferences.

In S2B partnerships, the value proposition typically revolves around the unique benefits and solutions that the research institution or university can provide to the industry partner. This could include access to cutting-edge research, specialized knowledge, intellectual property, or innovative technologies. Understanding the specific needs and objectives of the industry partner is essential for tailoring the value proposition to their requirements.

Researching the Potential Partner

Understanding the potential industry partner is crucial before negotiation. Research their background, culture, reputation, financial situation, market position, and objectives. Identify their needs, interests, concerns, and expectations from the partnership.

In S2B partnerships, thorough research of the industry partner is essential to ensure alignment between the research institution's capabilities and the partner's requirements. This includes understanding the partner's market position, competitive landscape, ongoing projects, and areas of strategic focus. Additionally, research should encompass the partner's technological needs, innovation goals, and potential areas for collaboration.

Setting Goals and Priorities

Define goals and priorities for the negotiation. Ensure they are realistic, measurable, and specific, aligned with the value proposition and the partner's needs.

In S2B partnerships, setting clear and achievable goals is essential for ensuring that the partnership delivers tangible benefits for both parties. These goals may include objectives

such as technology transfer, joint research projects, product development, or commercialization of intellectual property. Priorities should be established based on the strategic importance of each aspect of the partnership agreement, such as research scope, duration, responsibilities, risks, benefits, and costs.

Preparing the Proposal and Strategy

Based on goals and priorities, prepare the proposal and negotiation strategy. Outline the main features and benefits of the partnership agreement, as well as the expected contributions and obligations of each partner.

In S2B partnerships, the proposal should clearly articulate the value proposition, outlining the specific benefits and opportunities for the industry partner. This may include details about access to research facilities, expertise of research staff, intellectual property rights, and potential commercialization opportunities. The negotiation strategy should focus on building trust, fostering collaboration, and ensuring that the partnership agreement is mutually beneficial for both parties.

Conducting the Negotiation

Follow best practices during the negotiation to achieve a positive outcome. Establish a friendly and respectful tone, actively listen to the partner's feedback, and present the proposal confidently and compellingly.

During S2B partnership negotiations, it is essential

to maintain open communication and collaboration between the research institution and the industry partner. This involves active listening, understanding the partner's needs and concerns, and addressing any questions or objections they may have. The negotiation process should focus on finding common ground, exploring win-win solutions, and building a strong foundation for future collaboration.

Finalizing the Agreement

After reaching an agreement, finalize and formalize the partnership agreement. Review and summarize the main points and terms, document the agreement in writing, and have it signed by both parties.

In S2B partnerships, the finalization of the agreement marks the beginning of a collaborative relationship between the research institution and the industry partner. The agreement should clearly outline the rights, responsibilities, and expectations of both parties, including details of research collaboration, intellectual property rights, commercialization strategies, and financial arrangements. Once the agreement is signed, both parties should work together to ensure its successful implementation and ongoing management.

Part 5: Management of research and implementation projects

5.1 Technology Readiness Levels TRL

Description, definition and examples

Technology Readiness Levels (TRL) is a methodology used to assess the maturity of a technology throughout its development stages, from early conceptual research to operational implementation. The TRL scale has nine levels, with TRL 1 representing the lowest level of technology readiness and TRL 9 the highest. The TRL levels help determine how much work has been done and what remains to be done to bring our idea to market.

The TRL scale can be broken down into

1. basic research, which includes level 1

2. industrial research, which covers levels 2-6

3. development, which covers levels 7-9

Technology Readiness Level 1

This is the lowest level. Creative thought is defined, the concept of which is not ready. Technology is in the theoretical stage. At this stage, new phenomena and properties are discovered through basic scientific research. The technology is not tested in any practical application. Also, solutions that could be protected by law are not created at this stage.

Example: Inventing a material with interesting properties without specifying where this material could be used.

> **In the field of health** (medicine, pharmacy, nutrition, food for special nutritional conditions, dietary supplements): Identification of the opportunity (examples: atopic dermatitis, cancer, gastroesophageal reflux, Alzheimer's and others).
>
> Examples for the healthcare sector: Identify the pathology for which you want to develop a drug, food for special nutritional conditions, a food supplement or a medical device.
>
> Establish the state of knowledge regarding treatments for the respective pathology, using scientific databases, for example, PubMed, Web of Science and intellectual property/patent or patent application databases - WIPO, Epicene, OSIM, Patent Google, USPTO, PQAI and others). Studies of pathogenesis and pathophysiology related to humans and laboratory animals.

Technology Readiness Level 2

The concept is based on a specific application. However, no tests have been carried out to confirm the assumptions made, so the concept remains abstract.

Example: The material could be used, for example, as a bicycle tire

For the health field (medicine, pharmacy, nutrition, food for special nutritional conditions, dietary supplements): Development of hypotheses and experimental designs.

Example: Identifying and writing research ideas and experimental projects. Establishing the design with the first research ideas and testing the research hypothesis.

For inventions whose effectiveness is verified in vivo (preclinical or clinical), when establishing the design of the study, it is recommended to centralize the methodologies published in the specialized literature.

- Examples for preclinical studies: animals on which other similar research studies have been carried out (rodents, dogs, cats and others): species, line/breed, age, sex, number of animals, number of batches and number of animals per batch, the method of inducing the pathology, the period of treatment or nutritional intervention, the monitored biomarkers, the mechanism of action of the medicine or food, whether the animals had adverse reactions or not, the microclimate conditions of the biobased/experimental research station where the animals were raised.
- For the development of medicines, foods or dietary supplements, the concept is formulated (examples: ointment, capsule, tablet, jelly, biscuits, drink or others) and the technology is analyzed in comparison with other technologies on the market identified in the development of the knowledge stage (specialized literature, scientific articles, patents).

Technology Readiness Level 3

Experimental work is intended to verify that the concept works as expected. Components of the technology are validated, but there is no strong attempt to integrate the components into a complete system. Modeling and simulation may be used to complement physical experiments.

The concept is based on a specific application. However, no tests have been carried out to confirm the assumptions made, so the concept remains abstract.

Example: Checking the processing properties of whether the material can be used to make a bicycle tire

For the health field (medicine, pharmacy, nutrition): identification and preliminary characterization of the objective (medicine, food for special nutritional conditions, dietary supplement). For example, if the objective is an ointment, the preliminary characterization may be of the type whether it will be hydrophilic or hydrophobic, or if it is a food, it may be of the type whether the food will be liquid, powder, jelly, biscuits, chocolate or another type of food. food. In the case of food supplements, the preliminary characterization may be of the type of whether it will be a tablet, capsule, syrup, jelly or other type. For all the previous examples, the preliminary characterization may also be whether they will be heat-treated or not, whether they will require special storage conditions such as refrigeration, shelf life to determine the type of preservative needed or the possibility of vacuuming to avoid refrigeration or freezing storage, so as to reduce the carbon footprint. Sustainability can be another preliminary feature of the product, especially in the case of certain food supplements and foods for special nutritional conditions.

The results of the laboratory research support the concept/innovation/objective established in TRL 1.

Preliminary efficacy is demonstrated in vitro and/or in vivo, according to the national and European legislative regulations in force. For example, in the case of preliminary verification in vivo, on laboratory animals. The favorable opinion of the Ethics Committee and the Authorization from the Veterinary Sanitary Directorate must be obtained. Following these in vitro and/or in vivo verifications, the first preliminary results emerge which represent the first proofs of the concept/innovation.

Technology Readiness Level 4

Components and their integration have been verified under laboratory conditions in a controlled environment, extending the scope of testing from the TRL3 level.

Example: Testing key material performance characteristics under different environmental conditions relevant to consumers, such as cyclists.

For the health field (medicine, pharmacy, nutrition):

Optimization of the drug, food or dietary supplement and in vivo demonstration of activity and efficacy: development of the preclinical study to test critical aspects such as acute toxicity, pharmacodynamics and pharmacokinetics, demonstration of in vivo activity and potential efficacy consistent with the intended use of the product (i.e. dose, duration, route of administration of the drug or dietary supplement or food as e.g. oral or enteral), establishing parameters and markers that will also be used in the clinical evaluation of the efficacy of the drug/food for special nutritional conditions/food supplement.

In TRL 3 and TRL 4, both pharmacovigilance and nutrivigilance can be monitored (of the drug, food or dietary supplement), especially if adverse reactions occur or the developed product interacts with certain drugs/foods that may negatively affect drug clearance and thus may lead to a decrease in the effectiveness of allopathic treatment and the quality of life of patients and their families, respectively in hospitalizations with the implicit increase in health system costs.

From a manufacturing perspective, it is recommended to produce a certain amount of laboratory scale (i.e., non-GMP (Good Manufacturing Practice)) of the proposed bulk and formulated product and store it under various conditions, such as normal, refrigerated conditions, freezing, or very close to heat sources. This type of storage can be very useful if patients/clients do not respect the storage conditions mentioned on the label in the case of foods for special nutritional conditions and certain food supplements, or in the package leaflet and/or the summary of a drug. This way the researcher/inventor can know what the cause is and whether the complaint is well-founded or not.

Technology Readiness Level 5

The technology is integrated, meaning core components have been combined with the actual supporting components in a simulated environment that closely resembles real-world conditions.

Example: The manufactured tire prototype connected to the rim is prepared for initial performance tests under realistic laboratory conditions.

> **For the healthcare sector** (medicine, pharmacy, nutrition): Advanced characterization of the developed product (drug, food for special nutritional conditions or dietary supplement) and initiation of the development of the Good Manufacturing Practices (GMP) process.
>
> Continuation of non-GMP in vivo studies and development of animal models and tests (genetic analyses, tests on reproductive function, or other analyses may be included).

In this stage, a scalable and reproducible manufacturing process adapted to GMP is developed. For food and food supplements, it is recommended to develop a HACCP (Hazard analysis and critical point) plan to identify and analyze possible food safety hazards and for which measures must be implemented in the manufacturing process to prevent them. Examples of stages where preventive measures must be implemented: receipt of raw materials, dosing of food additives, pasteurization, sterilization, baking, storage, transportation of finished products or other stages, depending on the product developed.

Also at this stage, the development of animal models for efficacy and dose variation studies continues. It is very important to know what happens at higher doses and what adverse reactions may occur. It is recommended to establish protective correlations and/or markers for efficacy for use in future GMP studies on animal models and to identify the minimum effective dose to facilitate the determination of the "humanized" dose once clinical data are obtained.

Performing analyses by analytical methods for product characterization and release, including assessments of potency, purity, identity, strength, sterility and quality, as appropriate. Demonstration of acceptable absorption, distribution, metabolism and elimination characteristics and/or immune responses in non-GMP animal studies, for medicinal products in particular. These tests are also necessary if the inventor or assignee wishes to submit the file to a national or European authority (e.g., EFSA or EMA) for approval for manufacturing and/or marketing in the European Union, where EFSA represents the European Food Safety Authority and EMA is the European Medicines Agency.

Industrial production: the development of processes for small-scale production, according to GMP, is initiated. At this stage, it is important to consider the minimum capacity of the leading/main equipment/machinery in the production line and its type, to ensure that the quality of the developed product is not negatively affected. The minimum capacity of the leading machine is important for establishing the quantities of raw and auxiliary materials needed, for establishing the number of packaging and labels needed, and more.

Technology Readiness Level 6

This stage marks the conclusion of industrial research, featuring a more advanced prototype than that at TRL 5, tested under simulated operational conditions. The prototypes at this level are closer to the final production version.

Example: Bicycle tires are mounted and tested on a simulated road using specialized equipment or platforms.

For the healthcare sector (medicine, pharmacy, nutrition): GMP pilot batch production, submission of dossiers to local or national authorities and phase 1 clinical trials

Manufacture of GMP-compliant pilot batches. Preparation and submission of the newly developed and reviewed product dossier to local/national/European authorities and conduct of monocentric or multicentric phase 1 clinical trials.

Animal models: Further development of animal models through toxicology, pharmacology and immunogenicity studies.

Tests: Establishment of tests for production quality control and immunogenicity, if applicable.

Manufacturing: Manufacturing, releasing and performing stability testing of bulk and formulated products in accordance with GMP in support of clinical trials.

Target product profile (drug, food for special nutritional conditions or dietary supplement): Updating the target product profile, as appropriate.

Devices: Prototype system/device demonstrated in an operating environment. Clinical testing may be required to demonstrate safety. Depending on the classification of the device, pre-market approval or pre-market notification may apply.

The product (drug/food for special nutritional conditions, dietary supplement) meets industry expectations.

Determination of the safety and pharmacokinetics of the clinically tested developed product. It meets the requirements of external stakeholders.

Technology Readiness Level 7

This stage marks the beginning of development, where the prototype is tested under full operating conditions.

Example: A tire fitted to a bicycle is tested on a real road.

For the healthcare sector (medicine, pharmacy, nutrition): Scale up, initiate GMP process validation and phase 2 clinical trials.

Perform animal efficacy studies, as appropriate. Perform phase 2 clinical trials.

Animal models: Refine the development of animal models in preparation for animal efficacy studies.

Testing: Validate tests for production quality control and immunogenicity, as appropriate.

Manufacturing: Scale up and validate the manufacturing process according to good manufacturing practices (GMP and HACCP for foods or food supplement) at a scale compatible with the legal or other requirements of the economic operator. Initiate stability studies of the product in a formulation, dosage form and container in accordance with the target product profile. Initiate validation of the manufacturing process and production of a pilot batch/lot.

Target product profile: Update the description of the target product (drug, food for special nutritional status, food supplement, medical device), as appropriate.

Devices: Conducting clinical safety and efficacy studies using fully integrated prototype version of the developed product or medical device in an operating environment. Data evaluated to support further development. Final product design is validated and final prototype and/or device for commercial use is produced and tested.

Industry conducts testing.

Expansion and initiation of GMP manufacturing process validation.

Technology Readiness Level 8

At this level the technology is mature and complete. It has been tested in the intended environment confirming its usability under the conditions assumed at TRL 2 and has the necessary market approvals with the most relevant constraints. At this stage, the prototype demonstration is completed, a pilot batch is produced, and technical and service documentation is created.

Example: confirmation, e.g., declaration of conformity assessment, that the tire is marketable. A statistical pilot batch has been tested by consumers.

For the health field (medicine, pharmacy, nutrition): Completion of GMP validation, HACCP plan and pilot batch production, essential animal efficacy studies or clinical trials and preparation of documents for approval or manufacturing and marketing license to local or national authorities.

Complete stability studies in support of the label expiry date (examples of physic-chemical, microbiological or other type of analyses).

In the case of medical devices, before commercialization, the documents must be sent to the national authorities in order to receive the favorable opinion/approval.

Technology Readiness Level 9

The technology is ready for commercialization and has reached its final form. It can be implemented in industry and mass production.

Example: A tire has been analyzed for life cycle assessment and is safe to use. A marketing campaign is initiated.

For the health field (medicine, pharmacy, nutrition): Post-license and post-approval activities - The actual application of the technology in its final form, under operational mission conditions and the launch of the product on the market.

In this stage, the products are marketed, and studies and post-marketing surveillance are carried out, including in the fields of pharmacovigilance for the pharmaceutical field (drugs) and nutrivigilance (food supplements and foods for special nutritional states).

The customer/economic agent controls the technology.

The importance of the TRL

TRL technology readiness levels play an important role across various sectors of the economy. They enable:

- **Risk Identification and Mitigation -** TRLs help identify potential risks associated with technology based on its development stage;
- **Budget planning** - to better target resources where they are most needed;
- **Project management** - the TRL levels assigned to specific tasks in the research agenda clarifies the R&D pathway, allowing clear objectives and milestones to be set and progress to be monitored;

- **Strategic planning** - long-term planning of technology development strategies to maintain market advantage or increase competitiveness;

- **Investment decisions** - a defined TRL indicates the maturity of the technology, enabling investors to make informed financial decisions;

- **Compliance Assessment-**TRLs help assess compliance with project funding competition guidelines;

- **Communication** - a common language among different communities and stakeholders increasing the likelihood of successful technology transfer and implementation.

Challenges and practices

Adaptation to industry specifics: TRLs were originally developed for the aerospace sector, which can make them difficult to apply directly to other sectors such as medicine, IT or energy. Each industry has its own unique requirements and characteristics. It is therefore important to adapt the definitions and interpretations of the different TRL levels to the specific industry and market constraints. The introduction of sectoral or even company-specific guidelines for the interpretation of TRLs can help to standardize technology assessment within an industry**.**

Lack of universal definitions: Each industry may have different interpretations of TRL levels, leading to discrepancies in the assessment of technology maturity. This variability can hinder cross-sector comparisons and collaborations**.** To reduce the subjectivity of the assessment, it is important to develop clear and detailed information for each TRL level.

Qualitative assessment: Although presented as an objective tool, TRLs often rely on qualitative assessments by experts. The subjectivity of these assessments can lead to inaccuracies in determining the true maturity of a technology, especially in complex and interdisciplinary projects.

Differences in interpretation: Variations in expert interpretation of TRL levels can lead to ambiguous results, potentially resulting in suboptimal decisions regarding technology development. Regular consultation with industry and technology experts during the TRL assessment helps to minimize these differences in assessment.

Complexity of the technology: Assessing Complex technologies that different components or require integration into large systems may be difficult to assess clearly using TRLs. The framework may not fully account for all development integrate many aspects, such as technology integration or adaptation to market changes. Integrating TRLs with project management methodologies such as Agile, Lean, PRINCE2 or Six Sigma to improve consistency of effort. However, this can be challenging, especially in large organizations with extensive management structures.

Lack of market context: TRLs focus on technological aspects often overlooking market**,** regulatory, or business readiness, which can be critical in certain sectors. A technology may be mature (high TRL) but not ready for the market due to the lack of an appropriate business or regulatory environment.

Alignment with corporate strategy: TRLs may not be easily integrated into an organization's internal decision-making processes, which can lead to friction between different departments (e.g., R&D vs. management) based on differing interpretations of TRL levels.

Resource requirements: Implementing TRLs in an organization can require significant resources, both human and financial. Establishing and maintaining an accurate TRL assessment system tailored to the specifics of the organization can be costly, especially for small and medium-sized enterprises.

Time consuming: The process of accurately assessing TRLs, especially for complex projects, can be time consuming, potentially lengthening decision - processes and delaying technology development — especially problematic in fast-paced markets.

Changing technology conditions: In rapidly evolving sectors, such as IT or biotechnology, the pace of change is very fast. The static nature of the TRL scale may struggle to keep pace with dynamic requirements and technological advances, necessitating constant updating.

Evolving standards and regulations: As technologies mature, industry standards and regulations change. TRLs do not always reflect these changes, impacting the accuracy of technology readiness assessments.

Evolving methodologies: As technologies advance and industries transform, the TRL scale needs to be updated or adapted to remain useful and relevant. Failure to evolve in this way can diminish its values as an assessment tool.

Cultural and regional differences: In an international context, it may face challenges due to cultural, legal and regulatory differences. This can complicate global projects where different regions may approach technology assessment differently.

Project life cycle: TRLs can serve as milestones throughout the project lifecycle, **facilitating** better monitoring of progress and decision making based on objective indicators.

Risk mapping: Integrating TRLs with risk management. By determining the level of TRLs organizations can identify potential risks associated with further technology development and allow for early countermeasures.

Document the process: It is important to thoroughly document the TRL assessment process so that all decisions are transparent and can be reviewed if necessary. This builds trust between teams and stakeholders.

Reporting and monitoring: Regular reporting on progress against the TRL helps to keep all stakeholders informed and enables a swift response to any delays or problems.

Technology portfolio management: In organizations developing multiple technologies simultaneously, TRLs can help manage a portfolio of technologies, helping to allocate resources to the highest priority or potential projects.

Feedback loop: Establishing mechanisms to gather feedback from TRL users in an organization or industry can help identify areas for improvement, enhancing the overall effectiveness of the TRL framework.

Selected examples of description of TRL levels in the medical and IT industry

Project: Development of a new cancer drug

TRL 1-3: Discovery and testing of new chemical compounds with potential anti-cancer properties.

Example: Discovery of a new protein kinase inhibitor in basic research.

TRL 4: Validation of the activity of new compounds in in vitro studies, on cancer cell lines.

Example: Laboratory tests to confirm the efficacy of an inhibitor in inhibiting the growth of cancer cells.

TRL 5: Preclinical studies in animal models, assessing toxicity and efficacy.

Example: Mouse studies showing tumor shrinkage without serious side effects.

TRL 6: Initiate phase I clinical trials to assess safety and dosing in a small group of healthy volunteers.

Example: Studies in 20-80 healthy volunteers to determine a safe dose of the drug.

TRL 7: Phase II clinical trials, assessing efficacy in a larger group of patients with a specific type of cancer.

Example: Trials in 100-300 patients to confirm the efficacy of an inhibitor in treating cancer.

TRL 8: Phase III clinical trials, confirming efficacy and safety in a large group of patients, registration of the drug.

Example: Multicenter trials involving 1000-3000 patients in different countries.

TRL 9: Drug launch, post-marketing surveillance.

Example: Drug available in pharmacies, monitoring of efficacy and safety in patients.

However, it is important to remember that clinical trials (TRL 6-8) are a time-consuming, multi-stage, complex and very expensive process.

Project: New Cloud Platform

TRL 1-3: Research into new cloud storage algorithms and technologies. Example: Development of a new data compression algorithm.

TRL 4: Validation of the algorithm under laboratory conditions, creation of first prototypes.

Example: Testing a compression algorithm on small datasets in the lab.

TRL 5: Test the technology in a simulated operational environment, evaluate performance.

Example: Testing on larger datasets and simulating real-world workloads.

TRL 6: Demonstrate the cloud platform in a pilot environment, integrate with other systems.

Example: Deploying the platform in a technology company for beta testing.

TRL 7: Testing in a real operational environment, with real users.

Example: Deployment of the cloud platform in several companies in different industries.

TRL 8: Completion and qualification of the system, preparation for commercialization.

Example: Obtaining security and compliance certification.

TRL 9: Full operational implementation, commercialization.

Example: A commercially available platform offered to business customers worldwide.

5.2 The research hypothesis, the results of the project and the current state of the art

Description of the research hypothesis

Rationale

- Purpose: The hypothesis should clearly state what the research project aims to achieve, addressing specific questions or solving specific problems.
- Evidence-based: The hypothesis should be grounded in existing scientific literature and research identifying gaps or inconsistencies in knowledge that the project aims to address.

Content

- Concreteness: A clearly stated hypothesis that can be tested experimentally.
- Testability: Must be confirmed or rejected on the basis of the data collected.
- Variability: A clear statement of the independent and dependent variables.

State of the art

- Conduct a literature review to identify current trends, available technologies, current research and findings.
- Indicate how the hypothesis addresses unmet needs or gaps in knowledge.

Comparison with competing products or services

- Competitor analysis: Review existing products/services, noting their benefits and limitations.
- Identify how the proposed study has the potential to improve on existing solutions.

Stages of the research agenda

Planning

- Determine the methodology: choice of research methods (experimental, observational, simulation).

- Preparation of the work plan and resources, including the technology, equipment and personnel required.
- Breakdown of work by TRL level
- Carrying out the research
- Use standard scientific methods (e.g., experiments, statistical analysis) to test the hypothesis.
- Monitor progress and document results at each stage.

Innovation

Defining the research hypothesis and conducting the research systematically and scientifically ensures that the hypothesis can be reliably tested and that innovations with market potential can be identified.

- Novelty assessment: Does the project bring new knowledge, technology or methods that have not been used before?
- Market potential: Does the project offer solutions that have the potential to significantly impact the market by improving efficiency, cost or accessibility?
- Social or economic impact: Can the research contribute to the development of new standards, regulations or practices?
- Comparison

Basis for comparison

- Identifying comparison criteria: Determining which features, characteristics and benefits are key to evaluating a product or service. Examples include performance, cost, durability, ease of use, energy efficiency, uptime, safety, etc.
- Competitor Assessment: Performing an analysis of available competing solutions, considering their strengths and weaknesses.

How to benchmark

- Benchmarking: Gathering data on current solutions, for example through literature reviews, market research, user testing or technical analysis.
- SWOT analysis: Identifying the strengths and weaknesses of the new solution in relation to the competition (market opportunities and threats).

What to compare

- Technical parameters: such as performance, response time, efficiency, robustness, etc.
- Functionality: innovative features and benefits offered by the product/service.
- Cost: cost of manufacture, cost of ownership and end user price.
- Safety and compliance: health, environmental and regulatory aspects.

Parameterization of the comparison

- Quantitative metrics: Evaluation of measurable metrics such as speed of operation, energy consumption, product lifetime, etc.
- Qualitative metrics: Qualitative evaluation including user experience, ease of use, user satisfaction.

How to make a comparison

- Define specific criteria for the comparison and weight them according to their importance.
- Collect data from existing studies, reports and market data.
- Carry out comparison tests in real conditions or simulations.
- Use multi-criteria analysis tools (e.g., AHP multi-criteria analysis) to evaluate and compare potential benefits and features.

How to carry out the analysis

- Literature review: Identify recent publications, scientific articles, reports, patents and standards related to the research area. Determine which research is considered seminal or key.
- Trend analysis: Examine current research directions and technologies being developed by competitors.
- Identify knowledge gaps: Identifying which aspects of the topic have not yet been researched or are poorly understood.

What to look out for

- Credibility of sources: Use of peer-reviewed articles, recognized journals, industry reports.

- Timeliness of information: Focus on the latest data and trends to ensure the hypothesis aligns with current knowledge.

Best practice

- Structured analysis: Organize the literature review around key themes or research questions.
- Accurate documentation: Record all relevant sources to support claims.
- Critical appraisal: Evaluate the quality of research, methods and findings to avoid basing a hypothesis on flawed or weak foundations.

What to avoid

- Over-reliance on a single source: Use a wide range of sources to get a more complete picture.
- Outdated research: Avoid relying on older publications that may be out of date.
- Unclear or unverified sources: Rejecting material from uncertain or unverified sources.

A sound analysis of the current state of knowledge is key to understanding how a hypothesis fits into the existing research landscape and its chances of implementation.

Databases used in R&D

To analyses the current state of knowledge in relation to the research hypothesis, it is useful to use the following databases

- Google Scholar - a broad database of scientific articles from a variety of disciplines.
- ScienceDirect - access to peer-reviewed scientific articles and journals.
- IEEE Xplore - a key database for technology and engineering, including automotive composites.
- Web of Science - a comprehensive source of citations and scientific articles
- Patents: Google Patents or European Patent Office (EPO) - allow you to search for existing patents and patent applications.

Example of analysis and good practice

Subject: Development of an innovative lightweight, durable composite material for automotive applications.

- **Literature review:** Review of articles on lightweight composites (e.g., CFRP - Carbon Fiber Reinforced Polymer) used in the automotive industry in databases such as IEEE Xplore and ScienceDirect.

- **Patent analysis:** Search for existing patents on automotive composites on Google Patents or EPO.

- **Technology benchmarking:** Assess the performance of current composites (e.g., tensile strength, weight, manufacturing cost) and compare with proposed innovations.

- **Innovation assessment:** Identify innovative features (e.g., improved strength, lower production cost, corrosion resistance) compared to current solutions.
    - This analysis determines whether the innovative composite product adds value to the market and has the potential to replace existing technologies.
    - How to verify innovative features
        - Determine the parameter of the feature that demonstrates innovation
        - Define the baseline and/or competitive value of this feature
        - Define the innovative value of that feature

- **Review industry standards:** Review current standards and requirements for automotive composites (e.g., ISO, ASTM) to understand the characteristics new materials must meet.

- **Market trends Analysis:** Monitor market reports and industry research (e.g., McKinsey, Deloitte) to understand the demand for lightweight automotive materials and future developments.

- **Consult with experts:** consult with industry experts to gain practical insights into innovation potential, technical challenges and market implementation opportunities.

- **Identify research gaps:** Focus on areas where there is a lack of research or conflicting data, indicating opportunities for a new product.

- **Good practice**
    - **Take a systematic approach:** Conduct the analysis according to key themes such as materials, production methods, applications and cost effectiveness.
    - **Transparency:** Document the sources and methods of analysis to ensure the reliability of the results.
    - **Critical thinking:** Evaluate not only the results of the study, but also the methods and context in which they were conducted.

- **Pitfalls to avoid**
    - **Overlooking recent research:** Outdated data can lead to incorrect conclusions.
    - **Focusing too much on one technology:** Losing sight of the broader market and technology context can limit the innovation perspective.
    - **Ignoring the market perspective:** Limiting the analysis to technical aspects without understanding market needs and trends.

By applying the above steps and good practices, a state-of-the-art analysis can be effectively carried out in the context of R&D work, allowing a better understanding of the feasibility and innovativeness of projects.

5.3 Working with the business community before, during and after the project

Working with the business community before the project starts

A research topic to be developed for implementation should have its genesis in the identification of a market need for the solution to be developed. Before starting the project, current market trends and consumer needs should be verified so that the result can be commercialized. A partner for the identification of market needs is industry. They have extensive and specialized knowledge of their area of activity and experience of operating in the sector. A researcher who selects a research topic on the basis of an analysis of scientific literature should discuss the practical usefulness of this topic with companies operating in the relevant field. Interaction and exchange of experience in a field in which both parties are specialists - the researcher from the point of view of scientific achievement and the entrepreneur from the point of view of serving the market - creates a synergy effect characterized by the accuracy of the diagnosis and the effectiveness of the solution developed.

Innovative ideas in business are the basis for gaining a position on the market and beating the competition.

Novelty attracts the interest of customers, provides an opportunity to dynamically mark one's presence in the industry, and allows one to develop solutions that outperform competitive offers.

Introducing market elements into a project should start as soon as the idea germinates in the mind of the initiator. As the definition of innovation crystallizes, there should be a better definition of the need that the project outcome is intended to satisfy.

The way to market an innovation should be defined in the initial phase of the project and adapted to changing market needs and expectations.

If we do not know how to define the main points of the implementation strategy in the initial phase of the project, beyond the concept phase, it is most likely that our project will not be suitable for implementation.

Although research teams complain about the difficulties of contacting entrepreneurs, and entrepreneurs often report negative experiences of collaborating with universities and research institutes, both sides should strive for mutual contacts, exchange of experiences and agreement on common goals, as scientists need inspiration from industry and industry needs innovation to survive and thrive in a competitive market.

Before discussing the details of the research programmed and the requirements of the selected market segment, it is good practice to first sign a confidentiality agreement between the research unit and the company, which will protect the confidential information exchanged and provide a safeguard against potential misuse.

Once agreement has been reached on the topic and purpose of the research, a decision is made to jointly implement the project. Projects may be carried out with the help of public funding sources available at regional, national and international level, or with own funds. While the use of state aid tends to be governed by rather rigid stipulations in the model agreements signed by the beneficiaries prior to the application, R&D projects financed from own resources of research units and enterprises are characterized by a high degree of freedom in the design of mutual relations and obligations.

The developed agreement is recorded in the form of a commercialization strategy. The strategy covers the range of activities from inception to completion of the project.

When developing a commercialization strategy, the following should be considered:

the timing and territorial scope of intellectual property protection

- the benefits and risks of publication by the R&D partners
- the changing state of the art
- trends in customer preferences
- the business environment
- the state of the law; expected changes

Once a project has been completed, it is very difficult to develop an effective strategy for commercializing its results if market aspects have not been taken into account during the project.

Important steps after the decision to jointly implement a project

- Determine whether the project will make use of the parties' existing knowledge and achievements - so-called background IP, possibly proprietary know-how;
- Clearly define the tasks to be performed by the project participants;
- Determine how ownership of IP developed in the project will be shared;
- Determine who will be able to use the project results and to what extent;
- Determine whether rights to IP will be transferred at the end of the project.

Transparent and complete communication should be maintained by both parties throughout the project. The results of the tests should be communicated to the business partner as soon as possible in order to check whether the results obtained satisfy the parameters expected by the market. Any discrepancy between the desired results and those obtained should be analyzed and, if necessary, modify the characteristics of the target product according to public acceptance - e.g., by changing some of the functions and scope of the product. Obviously, the research agenda should be adjusted as the market changes. The research team should make both parties aware that any deviation from the planned results may lead to a significant change in the commercialization potential of the project outcome, which may prevent the entrepreneur from bringing the product to market.

Both parties should follow a pre-agreed commercialization strategy that systematizes subsequent tasks, also allowing for necessary changes. Successful commercialization of research results and project implementation are impossible without the active participation of the research team -as a substantial partner- and the company- which takes the market risk.

Successful marketing of an idea requires six well-planned sequences

1. Building a competent team

Commercialization is a complex activity that must encompass all aspects of the project. A successful launch requires a team of specialists from various disciplines. It’s not enough to have people who excel in creating innovative product or service concepts; effective

innovation also requires reliable subject matter partners, especially at the beginning of the process, as well as people with full business competencies, including marketing, sales, finance, production and logistics.

An industry partner involved in the project can be a substantive partner in this respect.

2. Market analysis and differentiation

Market analysis, particularly a thorough analysis of the competition, is essential for a precise definition of the offer.

If the idea is to be innovative, it must stand out and not be easily replicated by others. This involves a complex process of designing unique, measurable, credible and provide tangible value to the target audience. The entire communication and brand strategy will be built around them. This stage is the responsibility of the research team, but it must incorporate suggestions from the business/industry partner.

3. Analysis of examples

It's beneficial to build on the successes of predecessors rather than starting from scratch. Analyzing examples of successful implementations and drawing conclusions can make the job easier. Most successful projects have been commercialized by well-rounded teams with commercial, business and investor experience. Solid sources of marketing experience allow for the development of an in-depth understanding of the needs targeted by the end product, and studying the stories of successful start-ups is a must.

4. Stable funding (e.g., through KIS)

In the early stages of commercializing an idea, a stable budget is crucial. Until the process has been completed and stabilized, the venture must have a financial guarantee.

Capital must be provided for the creation of the prototype, for its first successful sale and launch, and for further development. There must be no sudden shortage of funds until a stable income is generated.

The budget for the whole venture must be carefully planned.

It is advisable to divide it into successive phases and to have a contingency budget to be used only in exceptional situations.

5. **Proving the credibility of the project**

Proving the project's credibility to business partners and the market is a critical step in marketing the project outcome, thus building the first RTB (Reason To Believe).

RTB is a supporting argument in commercial discussions.

If compelling competitive differentiators have been successfully combined and the value of the innovative solution effectively presented, the next step can be taken. The success of this step depends on the synergy between the business partner and the research team.

6. **Communication and sales at scale**

Turning the first victory into a mass success requires highly developed marketing and sales skills. Production capacity must also be maintained to keep pace with rapidly growing sales and increasingly demanding customer service.

Sudden success can exceed expectations and create new needs for which the entrepreneur may not be prepared. In this final stage, the synergy of all the company's skills, which begin to interact effectively, in parallel and in the long term, becomes crucial.

The success of the commercialization phase depends mainly on the skills and determination of the entrepreneur.

(Source: Medical University of Gdansk; www.kierunekbmp.pl)

Working together after the project

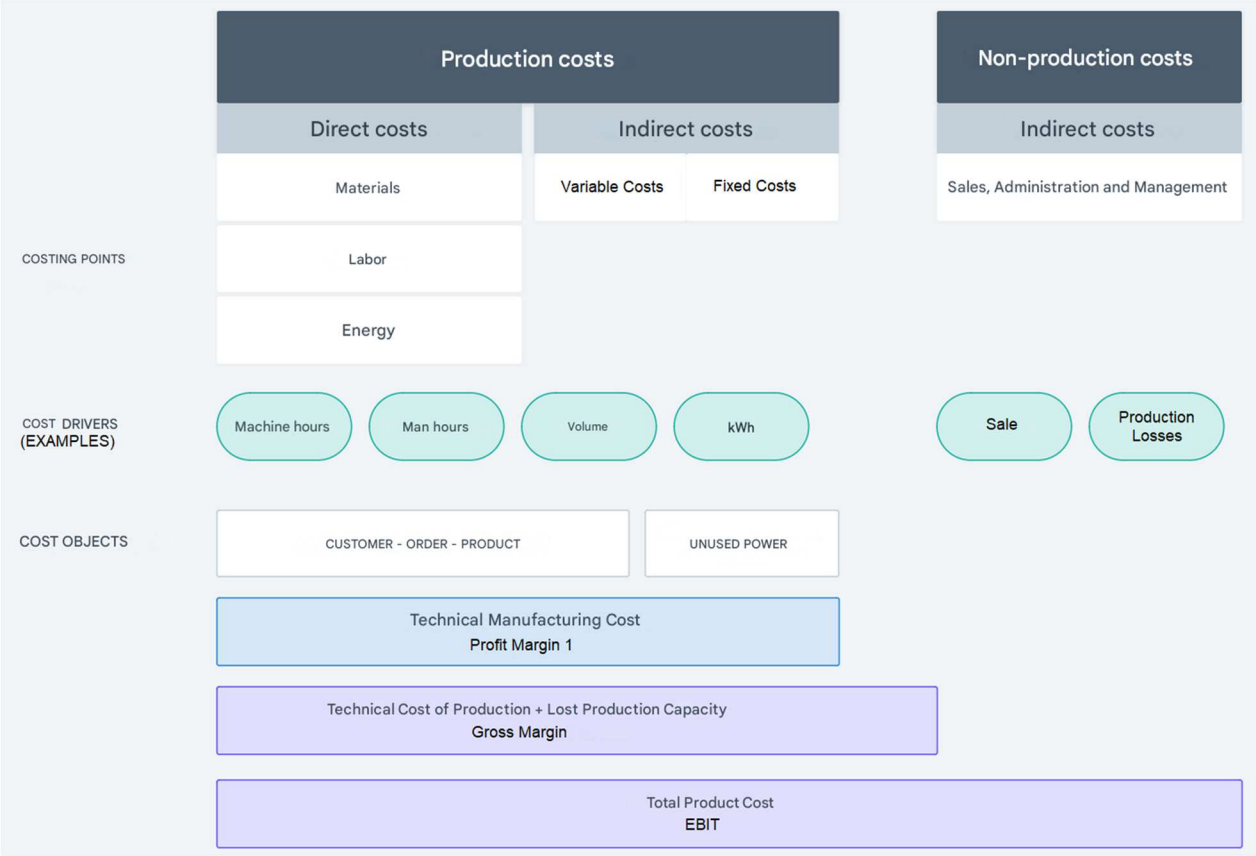
The end of a project should not mark the end of collaboration between stakeholders. The launched product will require modifications, improvements and adaptations to the changing needs of the audience. Partners in the commercialization process should monitor market reactions to the launched product, both positive and negative. Positive feedback may lead to the development of a better version of the product, which will increase market share and thus revenues.

Negative feedback should prompt the improvement of the criticized features, as passivity from the producer and originator could halt sales and cause losses.

5.4 Technical cost of products manufacturing (TCPM)

Definition and purpose

The technical cost of products manufacturing is the total cost of producing a product, encompassing all costs associated with the production process. This includes both direct and indirect costs. The calculation of the PTOM allows the company to evaluate the efficiency of the production process, make decisions on the profitability of production, plan the pricing policy, develop sales strategy, and manage current resources more efficiently.



Rys.1 źródło: ttps://www.vizyble.com/wiedza/wycena-kosztow-wytworzenia-produktu-kluczowym-narzedziem-zarzadczym-w-przedsiebiorstwie-techniczny-koszt-wytworzenia-tkw

Use in production planning and management

The Technical cost of products manufacturing (TCPM) is critical at several stages of production planning and management:

- **Production planning** - at this stage TCPM helps to assess the costs associated with different production options and to select the most cost-effective solutions.
- **Budgeting and cost control** - knowledge of TCPM enables accurate budgeting, cost control and identification of areas where savings can be made.
- **Pricing policy** - based on the TCPM, the company can set prices for its products, considering both costs and the planned profit margin.
- **Profitability analysis** - TCPM is used to analyses the profitability of producing specific products or product lines.

Components and stages of the TCPM calculation

TCPM consists of several basic elements:

- **Material costs** - the cost of raw materials, semi-finished products and other materials directly consumed in the production process.
- **Labor costs** - wages and salaries of employees directly involved in production, including non-wage costs (e.g., insurance, social benefits).
- **Machinery costs and depreciation** - costs associated with the operation and maintenance of machinery and depreciation of production equipment.
- **Energy costs** - the cost of the energy required to operate machinery and lighting in the production process.
- **Production overheads** - other costs associated with maintaining production, such as building maintenance, stock management, etc.

Steps in calculating the TCPM:

- **Data collection**
    - Identify and collect all direct costs associated with production, such as material costs, employee wages, machine depreciation, etc.
    - Include indirect costs such as energy costs, maintenance costs of the production facility, management costs.

- **Cost per unit calculation**
  Allocate the collected costs to individual stages of production or to production units, depending on the chosen calculation method (order-based, process-based, unit-based).

- **Analysis of the results**

  - Compare the calculated technical costs of manufacturing products with sales prices and budgeted costs.
  - Assessing whether the current cost structure is optimal and identifying potential areas for improvement

- **Implementation of optimization strategies**
  Based on the analysis of the **TCPM**, decisions are made to implement changes in production processes, renegotiate contracts with suppliers or introduce new technologies to reduce costs.

Methods for calculating the technical costs of products manufacturing

1. **Commissioning calculation method** - costs are allocated to a specific production order to determine the exact cost of producing a particular product.

   This method is mainly used in one-off or small batch production, where each product or series of products is treated as a separate production order. Costs are allocated directly to a specific order.

   General formula: **TCPM = MC + LC + MWC + MOC**

   Where:

   - TCPM – **technical cost of products manufacturing**
   - MC – material costs (raw materials, direct materials)
   - LC – labor costs (salaries, insurance and benefits for production workers)
   - MWC – machinery wear costs (depreciation, repair and maintenance costs)
   - MOC – manufacturing overheads (fixed overheads per order)

   Example of the calculation of the TPCM using the order method:

Assume that the cost of materials is MC is 10,000$, labor costs LC are 5,000$, machinery wear costs MWC are 2,000$, and manufacturing overheads MOC are 3,000$.

TCPM = 10,000 + 5,000 + 2,000 + 3,000 = 20,000

2. **Process costing method** - costs are allocated to individual production processes, which is effective in mass production where it is difficult to allocate costs to individual units of a product.

A method mainly used in mass production where the production process is repetitive, and costs are allocated to individual process steps and then divided by the number of units produced.

General formula: **$TCPM = \sum(KM_i+KL_i+KZ_i+KO_i)/LPU$**

Where:

- MC_i – material costs at the i-th stage of the process.
- LC_i - labor costs at the i-th stage of the process.
- MWC_i – machine wear and tear costs at the i-th stage of the process.
- MOC_i– manufacturing overheads at the i-th stage of the process.
- NPU – number of produced units.

Example of calculating TCPM using the process method:

Let's assume there are three stages in the production process:

- Stage 1: MC_1 = 3,000 $, LC_1 = 1,500 $, MWC_1 = 500 $, MOC_1 = 700 $.
- Stage 2: MC_2 = 2,000 $, LC_2 = 1,000 $, MWC_2 = 300 $, MOC_2 = 400 $.
- Stage 3: MC_3 = 4,000 $, LC_3 = 2,500 $, MWC_3 = 700 $, MOC_3 = 900 $

Total for stages:

$\sum(MC_i + LC_i + MWC_i + MOC_i)$ = 3,000 $ +1,500 $ +500 $ +700 $ +2,000 $ +1,000 $ +300 $ +400 $ +4,000 $ +2,500 $ +700 $ +900 $ = 17,500 $

If the number of units produced is 500 then:

TCPM = 17,500 $/500 = 35 $ per unit

3. **Unit costing method** - the cost of each unit of product is calculated by dividing the total cost by the number of units produced.

   General formula: **Unit TCPM = Total costs / Number of units**

   Example of calculating unit TCPM**:**

   If total production costs are 100,000 $ and 10,000 units of the product are produced, then unit TCPM = 100,000 $ / 10,000 = 10 $ per unit

Tools to support the calculation of the technical cost of products manufacturing:

- **Production Management Software**

  Today's companies often use sophisticated ERP (Enterprise Resource Planning) software to manage production costs, including TCPM. This software automates data collection, costing and reporting to enable ongoing cost control and rapid decision making.

- **Scenario Analysis**

  Companies can use scenario analysis to predict how changes in material or labor costs, or changes in production scale, will affect TCPM and profitability. This enables them to prepare for different market situations and changes in demand.

- **Benchmarking**

  Comparing TCPM with similar costs at competitors (benchmarking) is useful in assessing whether a company is cost competitive. If a company has higher manufacturing costs than its competitors, this may indicate a need to optimize production processes.

Meaning of the technical cost of products manufacturing

Knowledge of the technical cost of products manufacturing is crucial to the management of a manufacturing company:

- **Increase efficiency** by identifying costs that can be reduced without compromising product quality.
- **Optimize processes** through TCPM analysis, more efficient production processes can be implemented.
    - **Optimize production costs**: Accurate calculation of TCPM allows companies to identify the elements of the production process that generate the highest costs. This makes it possible to implement optimization measures such as:
        - **Switching raw material suppliers**: The analysis of material costs (MC) can lead to the renegotiation of contracts with suppliers or the search for cheaper raw materials of similar quality.
        - **Production automation:** High labor costs (LC) can lead to investment in automation or robotics of processes, reducing labor costs in the long term.
    - **Production planning:** TCPM is fundamental to the preparation of production schedules and financial plans. Knowing exactly what it costs to produce a certain number of units of a product allows for more efficient production planning. The company can assess in advance which orders are more profitable and what quantities are worth producing in order to maximize profit.
    - **Financial control and budgeting:** TCPM is a key indicator in the preparation of annual and quarterly budgets. By comparing actual production costs with budgeted assumptions, cost efficiency can be monitored on an ongoing basis and any necessary adjustments made. Regular monitoring of TCPM enables deviations from planned costs to be identified, which in turn enables a rapid response, e.g., by introducing savings or changes to the production process.
    - **Product pricing and pricing strategy**: Knowing an accurate TCPM is essential for product sales pricing. The price of a product must cover the cost of production and ensure a profit.
    - **Applying Lean Manufacturing tools** to minimize the technical cost of products manufacturing
        - **Kaizen** a philosophy of continuous improvement that encourages employees at all levels to look for ways to improve production processes.

- ✓ Impact on TCPM: Continuous process improvement, even by small steps, can lead to significant savings across production. Eliminating unnecessary steps and improving the efficiency of machinery reduces variable costs and also has the effect of reducing fixed costs in the long term.

- **5S (Sort, set in order, Shine, Standardize, Sustain**), a workplace organization system that aims to create a clean, tidy and safe working environment

  - ✓ Impact on technical cost of products manufacturing: Improved work organization and increased operational efficiency result in reduced waste of time and resources, thereby reducing direct and indirect costs associated with production

- **Just-In-Time (JIT)**, a manufacturing strategy that delivers materials and raw materials exactly when they are needed in the production process, minimizing inventory.

  - ✓ Impact on technical cost of products manufacturing: Reducing inventory reduces storage costs and the risk of waste, which in turn reduces material costs. In addition, more efficient management of raw materials can reduce the need for overtime and improve the use of production resources.

- **SMED (Single Minute Exchange of Die),** a technique aimed at reducing machine changeover times (production configuration changes) to single digits, i.e., less than 10 minutes

  - ✓ Impact on technical cost of products manufacturing: Reducing changeover times allows faster production changeovers and less downtime, resulting in better utilization of machines and labor. This in turn reduces the variable costs associated with downtime and unproductive energy consumption.

- **Kanban**, a production management system based on visual signals that indicate when to start a new production batch or material delivery.

- ✓ Impact on technical cost of products manufacturing: Improved synchronization of production and material deliveries minimizes overproduction and reduces costs associated with storing and handling excess raw materials.

- **To maintain competitiveness,** awareness of actual costs allows competitive pricing of products on the market.
    - **Set minimum selling prices** that cover production costs and make a profit.
    - **Develop a rebate policy**, knowing to what level the price can be reduced so that the company continues to make a profit.
    - **Segmenting the market** by offering products with different levels of quality and price to reach a wider range of customers.
- **Assessing Profitability and Viability.** The technical cost of products manufacturing enables companies to assess the profitability not only of individual products, but also of entire production lines or business units. Based on TCPM and margin analysis, decisions can be made to continue, restructure or close unprofitable production lines.
    - **The break-even point** is the level of production at which total costs (both fixed and variable) are covered by sales and profit is zero. Knowing this point is crucial because it allows a company to determine the minimum number of units it must produce and sell to avoid losses.

        - **Break-even point formula**: Break-even point (in units) = Fixed costs/(Unit price - Unit variable cost)

Example: If fixed costs are 100,000 $, the unit selling price is 50 $ and the variable cost per unit is 30 $, the break-even point in units is:

Break-even point = 100,000$ / (50$ - 30$) = 100,000$ / 20$= 5,000$ units This means that the company must sell at least 5,000 units of the product to cover all costs.

- **Investment decisions**, when planning to invest in new technology, production lines or machinery, an analysis of TCPM can estimate the costs associated with production on the new equipment. TCPM can also be used to assess the return on investment (ROI), which is crucial when making capital allocation decisions.

Example of the TCPM calculation in an R&D project

Project assumptions:

The project concerns the development of a new composite material to be used in aircraft construction. Costs will vary according to the TRL level. Assume that a unit (piece) of material is a certain amount of pilot production (e.g., 1 m² of composite).

Core costs:

- material costs (MC) - the cost of raw materials and consumables required to produce a unit of composite material.
- labor costs (LC) - the cost of the research team, engineers, technicians, etc.
- machinery wear costs (MWC) - costs associated with the purchase, hire or depreciation of equipment.
- overheads (OC) - other costs associated with the project, e.g., logistics, administration, testing.

Calculation of the technical cost of products manufacturing at different TRL levels:

TRL level 1-3 (conceptual and fundamental research phase):
At TRL level 1-3, the project is in the conceptual and basic research phase. At this stage, costs are mainly related to laboratory studies, simulations and small-scale experiments.

Assumptions:

- Number of units produced (pieces of material) = 10 pcs.
- MC (cost of materials) = 5,000 PLN
- LC (labor costs of the research team) = 50,000 PLN
- MWC (equipment and depreciation costs) = 10,000
- MOC (overhead costs) = 5,000
- Calculation:
  - ✓ Total TCPM =MC+LC+ MWC +OC

- Total TCPM =5,000+50,000+10,000+5,000=70,000
- Cost per material unit (piece):
  - ✓ Unit TCPM = Total TCPM /Number of units
  - ✓ Unit TCPM = 70,000/10=7,000 PLN/unit.

Justification of TCPM at TRL 1-3: High labor cost (LC) in relation to total cost as the project is focused on research and experimentation. Unit costs are high due to the small scale of production and the high proportion of fixed costs.

TRL 4-6 (Development, test and validation phase):

At TRL 4-6 the project enters the prototype development and testing phase. As the number of units produced increases, the cost of materials and testing increases, but the cost per unit may decrease due to the higher number of units produced.

Assumptions:

- Number of units produced (pieces of material) = 100 pcs.
- MC (cost of materials) = 40,000
- LC (labor costs of the research team) = 100,000
- MWC (equipment and depreciation costs) = 200,000
- MOC (overhead costs) = 15,000
- Calculation:
  - ✓ Total TCPM =MC+LC+ MWC +OC
  - ✓ Total TCPM =40,000+100,000+20,000+15,000=175,000

- Cost per material unit (piece):
  - ✓ Unit TCPM = Total TCPM /Number of units
  - ✓ Unit TCPM = 175,000/100=1,750 /unit.
  - ✓

Justification for TCPM at TRL 4-6: Lower unit costs compared to TRL 1-3 as costs are spread over a larger number of units. A Larger proportion of material (MC) and labor (LC) costs resulting from prototype production and testing. Increased overhead costs (OC) associated with validation.

TRL 7-9 (demonstration, certification and deployment phase):

At TRL 7-9, the technology is close to commercialization. Pilot production costs are increasing due to preparations for mass production, but unit costs may decrease due to further scale-up.

Assumptions:

- Number of units produced (pieces of material) = 1000 pcs.
- MC (cost of materials) = 200,000
- LC (labor costs of the research team) = 300,000
- MWC (equipment and depreciation costs) = 150,000
- OC (overhead costs) = 100,000
- Calculation:

✓ Total TCPM =MC+LC+ MWC +OC

  ✓ Total TCPM =200,000+300,000+150,000+100,000=750,000

- Cost per material unit (piece):
  ✓ Unit TCPM = Total TCPM /Number of units
  ✓ Unit TCPM = 750,000/1,000 = 750 /unit.

Justification for TCPM at TRL 7-9: Unit costs are significantly lower due to large scale production and more efficient distribution of fixed costs (MWC and MOC). High material (MC) and labor (LC) costs, but their impact on the unit cost is reduced by mass production. Significant production equipment costs (MWC) are amortized over a larger number of units, reducing the unit cost.

Summary of TKW differences by TRL level:

TRL 1-3: High unit costs (PLN 7,000/unit) due to small scale of production, high proportion of labor costs (LC) and depreciation of research equipment (MWC).

TRL 4-6: Lower unit costs (PLN 1,750/unit) due to higher production volumes and more efficient cost allocation.

TRL 7-9: Lowest unit cost (PLN 750/unit) achieved through large-scale pilot production, allowing fixed and variable costs to be spread over a larger number of units.

5.5 Project Risk Management

Project Risk Definition

Project Risk Management is the process of systematically identifying, analyzing, monitoring and controlling risks that may affect the achievement of project objectives. It is a key element of project management as it helps minimize uncertainty, improve decision-making and increase the chances of achieving the intended results.

The risk management process consists of **Several** steps:

- **Risk identification**, identifying all the potential risks that may affect the project. These risks can have various sources, including technical, operational, financial, schedule, resource, regulatory, etc.

- **Risk analysis**, assessing the likelihood and potential impact of each risk to identify which risks are most critical to the project.

- **Risk response planning,** developing risk management strategies to minimize or eliminate the negative impact of risks on the project. This includes both preventive actions and response plans when risks occur.

- **Risk monitoring and control**, regularly tracking and evaluating risks and the effectiveness of the management strategies implemented. Adjustments and new countermeasures are implemented as necessary.

- **Communication and documentation**, informing stakeholders of identified risks, management strategies and the current status of risks. It is also important to fully document the risk management process.

Risk Management Strategies

- **Risk avoidance**, taking steps to remove risk from a project altogether. For example, changing the scope of the project or using proven technologies rather than experimental ones.

- **Risk mitigation**, reducing the likelihood of a risk occurring or its impact on the project. Examples include additional quality testing, backup resources, or changing the schedule.

- **Risk transfer**, the transfer of risk to an external party, for example through insurance or contracting with a supplier to take responsibility for certain risks.

- **Risk acceptance**, the deliberate acceptance of a risk, usually when its potential impact is low and the cost of avoiding or reducing it would be too high. As part of this strategy, a contingency plan is put in place in case the risk materializes.

Risk analysis at different stages of the project

- **Inception stage**
    - Strategic risk, misjudging the viability of the project, poorly defined objectives or lack of support from key stakeholders;
    - Minimization, involvement of stakeholders in the decision-making process, thorough SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis, preparation of a business plan.

- **Planning stage**
    - Timing risks, underestimating the time needed to complete tasks, dependence on external suppliers;
    - Minimization, use of schedule management techniques such as Gantt chart, critical path analysis and preparation of time buffers;
    - Financial risk, underestimation of costs, exchange rate fluctuations, lack of liquidity;
    - Minimization, regular budget reviews, building a financial reserve, strict management of project changes.

- **Implementation phase**

    - Technical risks, technology implementation problems, hardware failures, system incompatibilities;
    - Minimization, testing, selection of proven technology solutions, strict quality control;
    - Operational risks, resource availability problems, staff turnover, lack of team skills.
    - Minimize, train, hire experts, maintain back-up resources.

- **Closure phase**

    - Compliance risk, failure to comply with all formal requirements, misreporting.

Key aspects of risk management

Effective risk management is based on the following activities

- Identifying and describing risks
- Assessing the severity and likelihood of occurrence
- Value of the risk - in terms of the potential loss that may be incurred
- Planning actions to avoid the risk
- Contingency plan - if the risk does occur

The following considerations influence the effectiveness of risk management

- **Stakeholder engagement**, regularly updating stakeholders and involving key stakeholders in the risk management process is crucial for ensuring their support and understanding of risks.

- **Accuracy and completeness of risk analysis**, accurate identification and assessment of risks enable effective risk management. Underestimating risks can lead to serious problems later in the project.

- **Flexibility in management**, the ability to adapt risk management strategies in response to changing project conditions is key. constant monitoring and willingness to modify risk management plans is essential.
- **Organizational culture**, risk management is more effective in organizations with culture of open reporting and rapid response to risks.

Risk management tools and techniques

To effectively manage risks in a project, professionals use a variety of tools and techniques to help identify, analyses and monitor risks, such as:

- **SWOT analysis**, this tool assesses the strengths and weaknesses of the project and identifies external opportunities and threats. SWOT is particularly useful at the project initiation and planning stages, as it helps to understand the context in which the project operates.

- **The Risk Matrix**, is a visual tool that helps to classify risks based on two criteria: probability of occurrence and impact on the project. Risks are classified as low, medium or high, making it easier to priorities countermeasures.

- **Root cause analysis**, a technique used to identify the root causes of risks. By understanding the root cause of the problem, actions can be taken to eliminate or reduce the risk.

- **Ishikawa diagram (fishbone diagram),** a tool used to identify and analyses the causes of problems. It is particularly useful when analyzing technical risks where various factors can influence the final outcome.

- **Scenario analysis**, a technique that involves imagining different possible scenarios of how events might unfold and assessing how each scenario might affect the project. This helps to prepare appropriate countermeasure strategies should any of these scenarios materialize.

- **Monte Carlo method**, an advanced simulation technique used to assess risk in projects. It allows the modelling of uncertainty in a project by generating multiple random scenarios and assessing how these variables could affect the project schedule or budget.

- **Brainstorming**, a group idea generation technique that helps to identify potential risks. It is valuable at an early stage when the project team is considering together what risks might occur and how to deal with them.

- **Risk Audit:** Regular risk reviews and audits are essential to assess the effectiveness of risk management and to identify new risks that may have arisen during the project.

Risks have different effects on the project. Their severity needs to be assessed and the impact they may have on the course of the project and its outcomes needs to be evaluated.

Risk analysis is best presented in the form of a risk matrix:

	A	B	C	D	E	F
1		Impact				
2	Likelihood	Negligible	Minor	Moderate	Significant	Severe
3	Very Likely	Low Med	Medium	Med High	High	High
4	Likely	Low	Low Med	Medium	Med High	High
5	Possible	Low	Low Med	Medium	Med High	Med High
6	Unlikely	Low	Low Med	Low Med	Medium	Med High
7	Very Unlikely	Low	Low Med	Low Med	Medium	Med High

Risk Colors				
1	2	3	4	5
2	3	4	5	5
1	2	3	4	5
1	2	3	4	4
1	2	2	3	4
1	2	2	3	4

We rank the risks on the chart as follows:

On the X-axis, we mark the impact of the risk on the course and outcome of the project: from a risk of zero, the impact of the risk increases as the value of X increases.

On the Y-axis, we mark the probability of a risk occurring, which increases as the value of Y increases.

Risks with low impact and low probability are colored green, risks with medium impact and medium probability are colored light green, risks with medium impact and medium probability are colored yellow, risks with medium impact and medium probability are colored orange and risks with high impact and high probability are colored red.

We monitor the risks at regular intervals and produce successive versions of the risk matrix showing their evolution over time.

As the project progresses, we may find that some risks change category or disappear, but new risks may also emerge.

Challenges and barriers

Despite the many tools and techniques available to project managers, risk management is not without its challenges. In real projects, there can be a variety of barriers to effective risk management, such as

- **Incomplete risk identification**, in some projects not all risks are identified at an early stage. This may be due to the inexperience of the team, the complexity of the project, or an overly optimistic approach to planning. As a result, unforeseen risks may materialize and affect the project in ways that could have been avoided.

- **Lack of Stakeholder Involvement,** if stakeholders are not actively involved in the risk management process, some key risks may not be adequately identified or managed. Stakeholders may have a unique perspective on potential risks that the project team may overlook.

- **Resistance to change** Many organizations resist implementing changes necessary to manage risk. This resistance may stem from a lack of understanding of the benefits of risk management, fear of additional costs or lack of resources. As a result, the organization may be exposed to risks that could be minimized or avoided.

- **Failure to communicate** Effective communication is key to risk management but can be difficult to maintain in practice. Lack of clear communication between the project team, stakeholders and management can lead to misunderstandings and incomplete implementation of risk management plans.

- **Lack of resources**, often project teams do not have sufficient resources (time, money, people) to manage risks effectively. This can lead to risks being overlooked or inadequately addressed, increasing the likelihood of problems.

- **Deferring risks to the future,** sometimes risks are identified but mitigation is deferred in the hope that the risk will not occur, or its impact will be minimal. This type of

approach can be very risky, especially in long-term projects where impacts can be cumulative.

Risk management, selected methods and trends

- **Agile** - With the rise in popularity of agile methodologies in recent years, the approach to risk management has evolved. In traditional projects, risk management is often seen as a separate phase, whereas in an agile environment it is an ongoing process and integrated into the day-to-day practices of the team.

- **An iterative approach to risk,** in Agile methodologies risks are identified and managed at each stage of the project, allowing rapid response to changing conditions and rapid adjustment of plans. Each iteration (e.g., a sprint in Scrum) ends with a retrospective, where the team analyses what went well and what might pose a risk in future phases.

- **With an agile structure**, agile teams can quickly adjust their actions in response to emerging risks. Instead of long-term risk management plans, Agile teams often use short-term strategies that can be quickly changed as needed.

- **Working closely with stakeholders**, Agile places a strong emphasis on continuous communication with stakeholders. Through regular meetings (e.g., daily stand-ups, sprint reviews), stakeholders are kept informed of progress and risks, enabling faster decision making and minimizing risk.

- One of the key elements of Agile is the **early delivery** of working parts of the product. This allows project assumptions to be quickly tested, risks to be identified and necessary changes to be implemented at an early stage, minimizing the risk of the entire project failing.

- **Continuous Improvement -** One of the key aspects of modern risk management is its integration with the philosophy of continuous improvement. This approach views risk management not as a one-off activity, but as an iterative process that is constantly evolving.

- **Retrospectives** allow teams to reflect on the risk management process and identify areas for improvement. This allows teams adapt their risk management strategies to the reality of the project.

- **Learning from mistakes**, as part of the continuous improvement philosophy, failures and mistakes are treated as valuable lessons to help the team manage risk better in the future. It is important that these lessons are formally documented and implemented in future projects.

- **Knowledge management,** organizations that manage knowledge effectively are better able to identify and manage risk. Creating knowledge repositories where risk cases and their management are documented is key to continuous improvement.

- **Trends** - Project risk management is evolving in response to changing market, technological and social conditions. Here are some of the trends shaping the future of risk management:

    - **Risk management automation:** More and more organizations are using advanced analytical tools and artificial intelligence (AI)-based systems to identify and analyses risks. These tools can predict potential risks based on analysis of historical data and current trends, enabling faster and more accurate responses to risks.
    - **Real-Time Risk Monitoring**: With the development of technology and digital tools, it is becoming possible to monitor risks in real time. This allows organizations to keep abreast of changing conditions and respond quickly to potential risks.

    - **Reputational Risk Management**: In the age of social media and instant information sharing, reputational risk has become one of the most important risks for organizations. Managing risks in this area requires special attention and advanced communication management strategies.

    - **Risk management in the context of sustainability**, more and more organizations are integrating risk management with sustainability goals. This involves analyzing the risks associated with the environmental, social and economic impacts of the business and seeking to minimize negative impacts in these areas.

Typical risks of research and implementation projects

Research projects are high-risk projects because there is no certainty that the research hypothesis will be confirmed and the intended effects will be achieved before the research is completed. In research and implementation projects, the risk of achieving the research objectives is compounded by the risk of meeting market expectations, which is essential for successful commercialization.

Risks typical of R&D projects can be divided into internal and external risks, introduced risks and imposed risks.

- Internal risks arise from the nature of the project and the organization of the work.
- External risks result from the actions of other stakeholders on the course of the project.
- Introduced risks stem from inadequate knowledge or failure to carry out part of the work.
- Imposed risks - are project conditions that are beyond our control.

From the project environment perspective, these risks can be divided into micro risks, medium risks, and global risks.

Micro-level risks - usually arise from the project organization and are mostly internal risks.

The main micro-level risks are:

- Risks associated with the departure of key personnel,
- Risk of making wrong assumptions,
- Organizational risks,
- Risk of poorly defined schedule,
- Cost risk (spending too much),
- Operational risk (we may not deliver the process),
- Risk of not making the installation efficient.

We minimize **the risk of understaffing or lack of experience in the research team** by clearly defining the tasks to be performed and recruiting capable individuals. If we do not have project staff with the skills best suited to the project, we minimize this risk by seeking external advice where necessary.

External risk: The selected contractor cannot complete part of the work on time. We minimize this risk by having a back-up contractor to whom we can assign that part of the project if necessary.

Introduced risk: Insufficient estimated budget to complete the study. We minimize this risk by including a financial contingency reserve.

Imposed risk: short timescale for research can be managed by careful planning and strict adherence to the timetable. Negotiating with the project's funder may also be an option.

Intermediate scale risks usually relate to the market aspects of the project.

Once the research phase of an R&D project has been completed, the risks associated with conducting the research will cease to exist, but there are still risks associated with bringing the research results to market, i.e., commercialization.

Risks typical of the commercialization process:

Intrinsic risks are the risk of not achieving the effectiveness of the technology/product. We minimize this risk by assessing the results of intermediate research stages in terms of their marketability and meeting the expectations of future customers. If the results of the research do not satisfy us, we try to change the research agenda to look for other characteristics of the product under development that may be a distinguishing feature of its suitability for the function for which we want to allocate it. It is important that this modified feature/function is still desired by the market.

External risks are barriers to entry. There may be a change in entry criteria because there has been a change in consumer awareness, their preferences or economic conditions have changed, or a competing product has entered the market in the meantime to meet their needs. This risk is always present in the process of bringing an innovation to market. The only effective way to minimize this risk is to use an agile management approach, where we try to deliver finished project components (e.g., research results) as quickly as possible to test their usefulness in the consumer decision-making process, and to react quickly and flexibly when changes in trends are identified.

Introduced risks are related to the marketisation of the project outcome, are e.g. inappropriate pricing of the marketed product. This includes both too low and too high an

input price. Setting the price too low may result in not achieving economic objectives, while setting it too high may create an economic barrier. This risk is often due to inadequate market understanding and business model development.

In general, this type of risk (introduced risk) in commercialization is almost always due to an inadequate understanding of the current market offer and consumer purchasing capabilities and/or an inaccurate development of the venture's business model.

Note:
Careful identification of the customer's current market offers and buying power, and the development of an appropriate business model for the venture, are two of the most difficult steps in the whole commercialization process to achieve and should therefore be given particular attention when bringing an innovation to market.

We minimize this risk by ensuring that

- the product has a clear competitive advantage
- the new product is introduced before competitors introduce similar products
- the company anticipates possible reactions from competitors
- the new product provides an opportunity to create barriers for competitors
- monitor competitors' reactions and take appropriate countermeasures if necessary
- the consequences of being a leader or a follower are anticipated.

Imposed risk - in the commercialization process this may take the form of the need for certifications and approvals, which may require additional specialized and expensive testing. In some cases, such as commercializing an innovation in the form of a medical device or pharmaceutical molecule, biocompatibility testing or clinical trials may be required. As it cannot be assumed that these tests will be successful, the decision to market a medical device involves accepting the risk, imposed by the regulatory authority, of not meeting the conditions required for the use of these products.

Macro risk is a global risk. An example of this is international competition in the speed and efficiency of research carried out simultaneously by several research centers on the same or a very similar topic. The first to complete the research and successfully commercialize the

result is likely to become the market leader, while the research investment of the other research centers may never be recouped. Fortunately, risks at the global level rarely affect the current research agendas of universities and institutes at the national level.