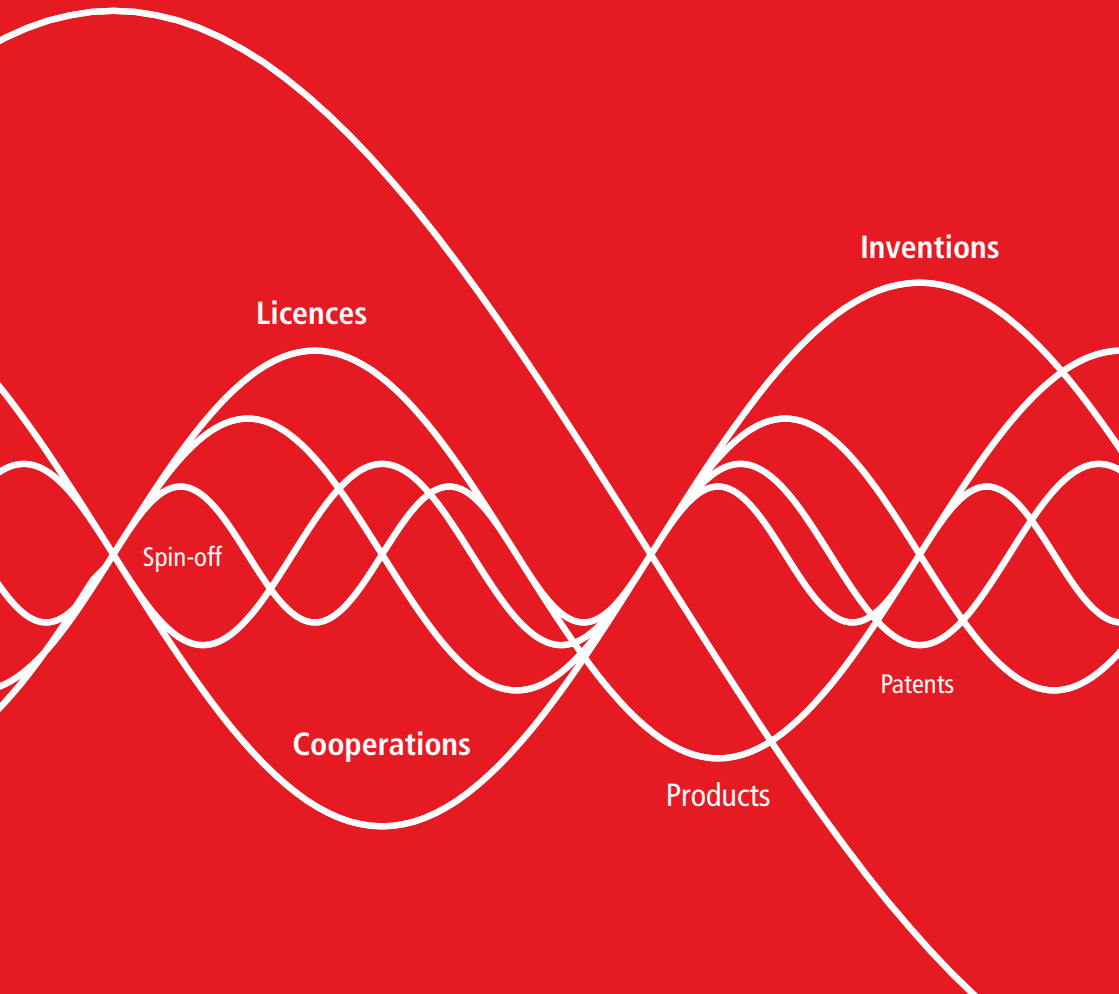
Technology transfer for academic research
A company of the LifeScience Foundation

ascenion

Your invention – your questions answered



What does Ascenion offer inventors?

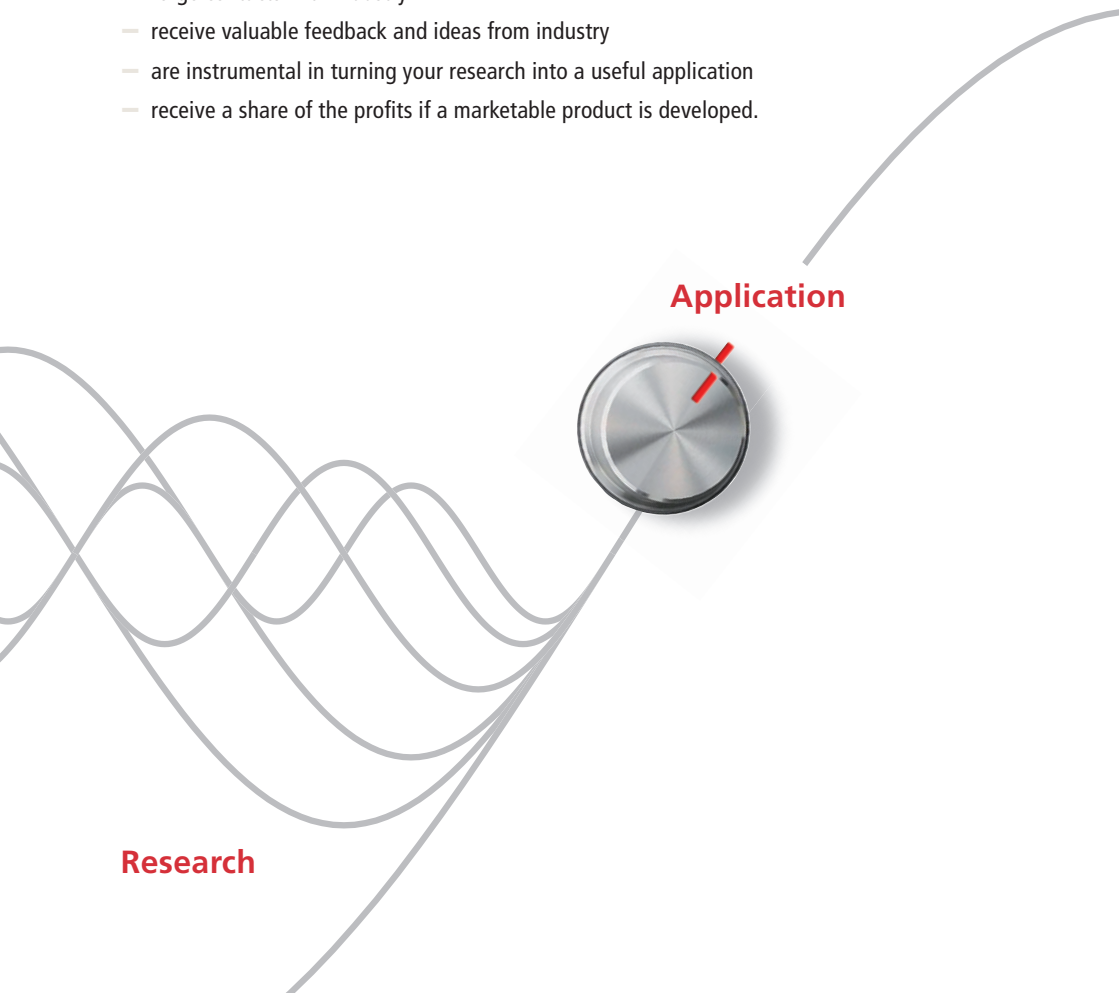
We help you turn your invention into a marketable product, working closely together with you and your institute. Simply come to us with your project!

We...

- ascertain whether your results are patentable, and if this would make economic sense
- develop with you a suitable patenting und commercialization strategy
- make contact with potential industrial partners
- negotiate licensing and cooperation agreements and monitor compliance.

You...

- gain an insight into relevant markets
- forge contacts with industry
- receive valuable feedback and ideas from industry
- are instrumental in turning your research into a useful application
- receive a share of the profits if a marketable product is developed.



Who may use our services?

Our services are available to all scientists working at our partner institutes who have an exciting, commercially interesting life-science project. This includes new therapeutic and diagnostic approaches, as well as research materials (e.g. antibodies, vectors, animal models), methods, software and medical technology products.

How much do Ascenion's services cost?

Our services are paid for by our partner institutes by a mixture of fees and performance-related bonuses. Virtually all of any surplus profits from Ascenion's operative business activities flow via the LifeScience Foundation to the institutes as grants for further research. Proceeds from commercialization flow directly to the institutes, which in turn pass on a share of these to the inventors. See the section at the end of this flyer for more details.

What may be patented?

An invention can be patented if it
a) is novel
b) involves an inventive step
c) is industrially applicable.

Novelty

In patent law, an invention is considered to be new if it does not form part of the 'state of the art'. 'State of the art' includes everything that has been publicly disclosed, no matter how or in what form: whether in journal articles, blogs and data bases, or at conferences in the form of presentations, posters or discussions, etc. In Europe, and now also in the USA, the deadline for establishing novelty is the day on which the patent application was filed, known as the 'priority date'.

Please inform us without fail at least 2–4 weeks in advance of any planned publication. The possible patenting and commercial development of your project may otherwise be compromised. Many institutes have established their own publication regulations that include pre-publication screening.

Inventive step

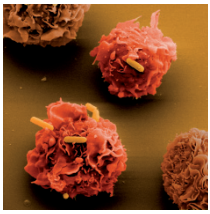
The second criterion, the inventive step, takes into account the intellectual achievement behind the invention. This is judged compared to what could reasonably be achieved by a specialist of average talent who has access to all published material in the field and who possesses good specialist knowledge and craftsmanship without being a leading authority. If the specialist could be expected to come up with the same solution as the inventor, then the inventive step is too insignificant for the invention to be patented. Ingenuity is what counts: for example, the invention whereby a piece of wire was bent to form a paperclip was granted a patent.

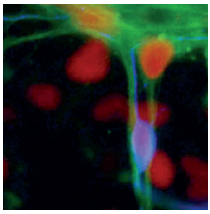
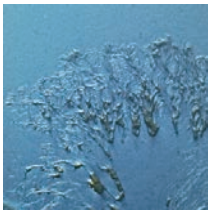
Industrial applicability

In general, the only inventions that fall at this hurdle are those that may not be used commercially under law. This applies, for example, to certain surgical or therapeutic procedures in human and veterinary medicine.

Invention or discovery?

An invention that fulfils all three of the above criteria is patentable. A discovery, on the other hand, is not patentable. A discovery is a naturally occurring substance or physical law that has been detected or recognized for the first time. An invention refers to the solution of a particular problem by technical means. There are however borderline cases: for example, if a particularly creative approach was required in order to isolate a naturally occurring substance and make it accessible, this can be regarded as an invention.



Who belongs to the team of inventors?

All those who played a significant part in the inventive process count as inventors. A scientist who merely carried out routine analyses during the development of a new procedure is no more entitled to belong to the team of inventors than the head of the research group, assuming he or she did not contributed directly to the invention. If a patent application is made, it must be made in the name of all the inventors. Otherwise severe difficulties may be encountered during the patenting process. In the USA, a patent may be subsequently denied, should it transpire that all inventors were not correctly stated.

What is patent worthy?

An invention is patentable when it fulfils the criteria named above. It is only patent worthy when a patent application appears worthwhile to the prospective patent holder. In order to ascertain this, we consider:

- the chances of being granted a high-quality patent
- the cost–benefit (the patenting and eventual development costs in relation to possible revenues from commercialization)
- the strategic goals of the institute

This last point can be decisive. Some institutes deliberately promote the patenting and commercialization of projects that would not be considered patent worthy from a purely commercial standpoint – for example, new approaches to the treatment of very rare diseases or diseases predominantly endemic in developing countries.

Is a patent required in order to market a product?

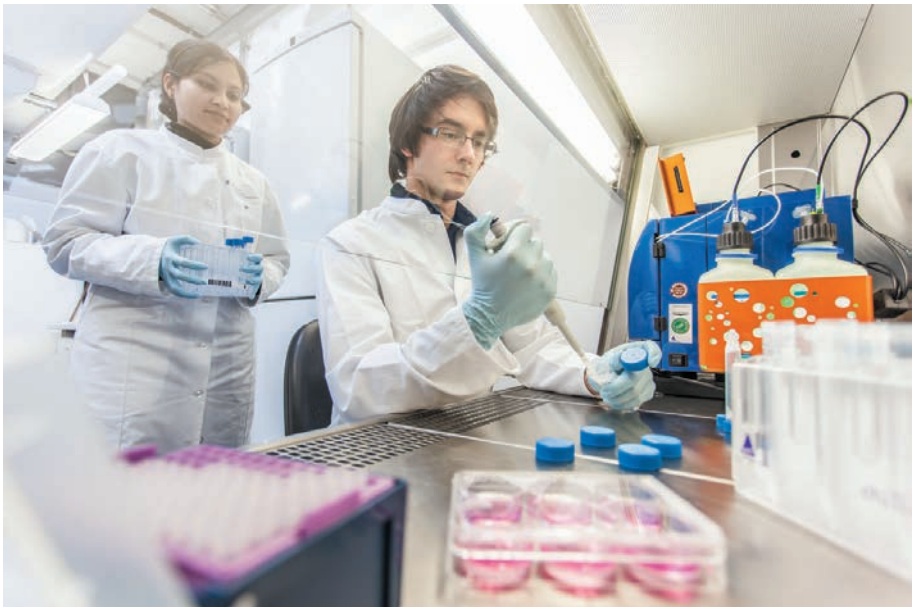
No. Unpatented materials, tools and animal models are often of great interest to the pharmaceutical industry. It is usually much cheaper and expedient for companies to license specific models from academia for a fee, than to invest themselves in the development of such tools. Exclusivity is not an issue here. In the case of potential therapeutic or diagnostic products, on the other hand, solid patent protection is necessary in order to secure a partner for further development. As the required investment will usually run into millions, product development is only interesting for pharmaceutical companies if they can secure exclusivity.

What use is a patent?

A patent grants the holder the right of exclusion. Without his permission, others may not use, make or sell his invention.
Of course, he may enter an agreement with third parties granting them the use of the invention. Depending on the patent holder's objectives and negotiating skills, this may be for defined applications or comprehensive use, for exclusive or non-exclusive use, or for a lower or higher licence fee. You can read more about the price of licences in one of the following sections. The public also benefits from a patent when it is disclosed. Eighteen months after the patent application, the application text with all details of the invention is made publicly available, thereby increasing public knowledge and potentially contributing to further technical advances. This is the basic principle of patent law: the right of exclusion encourages the inventor to put his invention into the public domain.

What is the scope of a patent?

The scope of protection is defined by the patent claims as they appear in the patent application. The art of maximizing the patent's scope lies in finding the best compromise between the following aspects, so that the claims:



a) are as detailed as possible
For example, each and every step of a procedure, including exact amounts and concentrations of each reagent used and details of all equipment should be included.

b) are as broad as possible
The patent claims should also be as general as possible, for example in relation to the methodological principle. This prevents the patent from being circumvented by the simple substitution of reagents.

c) have as little overlap with existing patents as possible
Overlap with existing patents does not necessarily prevent a patent being granted, but always compromises its commercial use. You must usually pay licence fees to the holder of the existing patent, in order to bring your own invention to the market.

Where does a patent apply?

Patent protection only applies in those countries in which the patent was filed and subsequently granted by the relevant authorities.

A patent can either be applied for separately in individual countries, or in a joint application to the European Patent Office for all European countries, or as a PCT application for signatory countries of the Patent Co-operation Treaty (PCT). The PCT application, however, is only a unified preliminary step of a process that must ultimately be completed by the national patent offices of the PCT states. The member states of the European Patent Convention have come up with a more convenient solution – here a single examination at the European Patent Office is sufficient.

The broader the application, the more comprehensive the protection – and the more costly the process. For this reason, it can make sense to file a priority-based application in one country. This secures the inventor the right to apply for patents for the same invention in other countries within a year, whereby the date of the first application counts as the priority date for determining novelty everywhere. Publications between the first application and applications abroad therefore present no obstacle to the latter being granted. The inventor also gains time to gauge the market value of his invention and to consider his territorial strategy.

How long does patent protection last?

A patent is valid for 20 years from the date of the priority-based application. In the case of approved medicines, an application can be made in some cases to extend the duration of protection for a maximum of 5 years.

Who owns the patent?

In Germany, the employer of the inventor or inventing team owns the patent, unless they decide otherwise. The process is as follows:

a) Notification

According to the German Employee Inventions Act ('Arbeitnehmererfindergesetz'), an employee must inform his employer of his invention immediately. The employer, usually a research institute or university, then has up to 2 months in which to request any missing information or documents pertaining to the invention.

b) Evaluation

As soon as they have received the complete notification of the invention, the employer has 4 months to evaluate the invention and decide whether or not they wish to claim it or release it.

c) Ownership by default

If the employer does not release the invention within this 4-month period, he automatically becomes the owner. However, ownership comes with responsibilities: the employer must file a patent application, in Germany at least, and give the inventor a share in any revenues arising from successful commercialization.

If the employer releases the invention, the inventor can make use of the invention as he sees fit, provided no other agreement has been made. He then bears all the associated costs and risks himself.

What are the chances of commercial success?

Only an estimated 5–7 % of patents are used commercially. This is not necessarily a reflection on the inventions themselves.

Only an estimated 5–7 % of patents are used commercially. This is not necessarily a reflection on the inventions themselves. It can be due to the personal or strategic interests of inventors or companies, but sometimes it is merely because the gap between research and industry is too great. In recent years, however, technology transfer organizations in co-operation with partners in research, industry and government have launched numerous initiatives in order to reduce or bridge this gap. Among the projects Ascenion has developed for its partners are:

Spinnovator:
a financing and support instrument for the market-oriented development of early-stage projects: www.spinnovator.de

BioVaria:
an international platform where research institutes present selected life-science inventions to industry: www.biovaria.org.

What are the options for commercialization?

Possibilities include licensing, sale, cooperation or founding a start-up. Together with the inventor(s) and institute, we determine the best options for each project in order to successfully bring it to the market. We have compiled information and advice for prospective entrepreneurs in a separate brochure (www.ascenion.de).

What determines the price of a licence?

Ultimately, the market. This is relatively uncomplicated in the case of materials, tools or model systems, which are usually licensed in return for an annual fee. The situation is more difficult for potential methods, diagnostics or therapies at an early stage of development. Crucial to the licensing conditions is the level of investment that the licensee will have to make in order to develop the invention for the market, and the risk they run of overreaching themselves. In the case of therapeutics, these investment sums can reach tens or thousands of millions, and the probability that a very early project then reaches the market is under 10 %. For this reason, the parties usually agree to a mixture of different types of payment:

One-off, up-front payment – due when the contract is signed

Milestone payments – due when pre-defined development milestones are reached

Share of profits – predefined percentage shares of profits in the event that the product reaches the market.

In general, the costs for the licensee increase the further down the development pipeline the product is, the more comprehensive the intended usage rights are (areas of application, geographical area, exclusivity) and the more parties there are who are seriously interested in obtaining a licence.




What share of profits does the inventor receive?

Most of Ascenion's partner institutes offer inventors a larger share of the financial proceeds than legally required. The 'rule of thirds' is often applied: after the deduction of a contribution towards patenting expenses, the proceeds are divided equally between the inventor, the research group and the institute.

If the institute does not have its own regulations, then the Employee Inventions Act applies. This stipulates that the inventor receives a percentage share of net profits, based on various factors, for example his or her position in the institute.

Further Information & Contact

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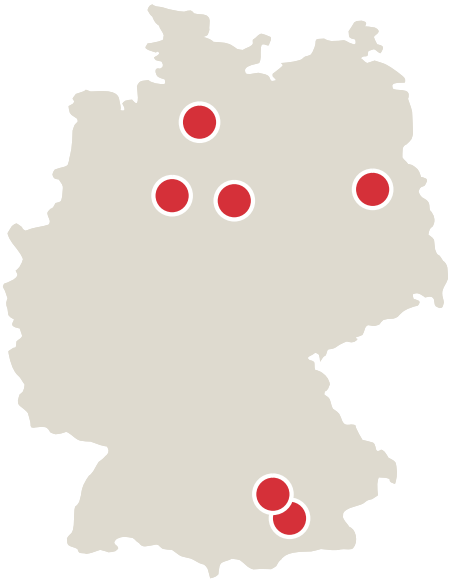

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