Three questions to...

... Mr. Markus Rieck LL.M.

Patent Attorney | Partner
Fuchs IP

Topic: Patent Registration in Life Sciences.

Question #1: What can and cannot be patented in life sciences?

Mr. Markus Rieck: As a general principle, any novel and inventive technical invention is eligible for patent protection unless it is specifically excluded by law. For instance, patents can be granted for genes, organisms, and biomarker-related inventions. Although methods of medical treatment, surgery, and diagnosis are excluded from patentability, the practical impact of these exclusions is often overestimated by scientists. In reality, there are frequent ways to secure protection for innovations in life sciences, even when their primary application falls within one of these excluded categories.

For example, while European patent law excludes methods of treatment for humans and animals from patentability, it does allow patents for substances and compositions, as well as for their specific uses in treatment methods. This means that if an invention involves the use of a therapeutically active agent in a novel way, it may still be patentable - even if the agent itself is already known and the inventive step lies in its use in a treatment method. This illustrates how inventors in life sciences can successfully navigate patentability exceptions.

Ultimately, the key question is not simply whether an invention can be protected, but rather how, when, and in what form a patent application should be prepared and filed. In my experience, inventor teams are often deeply engaged in their field and may be able to file several patent applications. It is essential to optimize the scope, costs, and filing sequence based on factors such as the stage of development, investor expectations, and available budget.

!LEVA Sciences GmbH
Im Schwarzenbach 4
79576 Weil am Rhein | Germany
Tel.: +49 (0)7621 95116 - 38
Contact Person:
Dr. Linda Ehm
Email: L.Ehm@levascience.com
Phone: +49 (0)151 28990473

Question #2: Who owns the invention if it was developed at a university or in collaboration?

Mr. Markus Rieck: Ownership of inventions is a critical consideration, especially during due diligence processes. Founders must ensure that they possess clear rights to the inventions they intend to patent. If licensing an invention, it is equally important to verify that the licensor has legitimate ownership of the licensed technology or drug candidate. All transfers of ownership should be meticulously documented, and any questions regarding ownership should be resolved as early as possible.

Generally, ownership is determined by inventorship: the individuals who create an invention are its initial owners. In most cases, inventors transfer their rights to another entity, such as their employer – an university, for example. The university may subsequently transfer ownership to a third party, such as a company.

In collaborative projects, the governing contract typically specifies how inventions are allocated – either to one party or jointly to both. It is essential to understand and review these contractual terms to ensure that ownership aligns with the intentions of all parties involved.

In practice, determining ownership can be complex, particularly when parties do not adhere to the terms of their agreement. Early clarification and diligent documentation are key to avoiding disputes and ensuring that ownership is properly established.

Question #3: What is a Freedom to Operate analysis, and when do I need one?

Mr. Markus Rieck: In patent law, a Freedom to Operate (FTO) analysis assesses whether specific actions – such as manufacturing or selling a product – might infringe existing patents owned by others. Conducting an FTO analysis is essential, as patent infringement can seriously disrupt a company's business operations.

Investors often request FTO information, and founders should be prepared to address related questions. However, a comprehensive FTO analysis can be prohibitively expensive for startups, since it requires reviewing large numbers of third-party patents and applications. To manage costs, it is advisable to begin with a focused analysis – examining the product and the most relevant jurisdictions first, while postponing less critical countries and manufacturing processes.

Typically, an FTO analysis will identify patents or applications that require attention. Some may be of uncertain validity or still pending examination. In certain cases, it may be possible to obtain licenses for third-party patents, which can even provide additional exclusivity for the company. For example, a third party may own a patent on an excipient used in a pharmaceutical formulation. Obtaining an exclusive license for a specific field of use of that excipient may prove to be very valuable. Therefore, FTO work not only uncovers potential risks but can also reveal new strategic opportunities.

!LEVA Sciences GmbH
Im Schwarzenbach 4
79576 Weil am Rhein | Germany
Tel.: +49 (0)7621 95116 - 38
Contact Person:
Dr. Linda Ehm
Email: L.Ehm@levascience.com
Phone: +49 (0)151 28990473

About Markus Rieck:

- Markus Rieck advises life science start-ups and technology companies on the development and enforcement of tailor-made patent strategies – from the initial application to a successful exit. His main areas of expertise are biotechnology, pharma, and antibody technologies, as well as opposition proceedings before the European Patent Office.
- He holds a degree in pharmacy and a Master of Laws in European intellectual property law, has been working in the IP field since 2004, and has been a partner at Fuchs IP since 2011. He is a German and European patent attorney, European trademark and design attorney, and a registered representative before the Unified Patent Court (UPC).
- As co-initiator of the Artificial Inventor Project (DABUS) and expert at Science4Life, he is actively involved in promoting innovation and start-ups in the life sciences sector.

Contact:

Markus Rieck LL.M.
Partner | Patentanwalt

Fuchs Patentanwälte Partnerschaft mbB
Tower 185 | Friedrich-Ebert-Anlage 35-37
60327 Frankfurt am Main | Germany

Phone: +49 / 69 / 20 43 67 9-0
Email: markus.rieck@fuchs-ip.eu
Website: www.fuchs-ip.eu

About Fuchs IP:

As a law firm specializing in strategic patent issues, we support companies i.a. in the life sciences sector in effectively protecting their innovations and securing their technological advantages. For over 85 years, we have been combining scientific expertise with legal precision and strategic thinking.

Our experienced team develops creative patent strategies that protect your research results, strengthen your market position, and increase the value of your IP portfolio in a targeted manner. From biotechnology to medical technology to pharmaceuticals—we understand your technology and accompany you from the initial idea to the successful enforcement of your intellectual property rights.