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Patents and Licences for MedTech

According to the latest statistics of the European Patent Office, medical technology continues to be the category with the second highest number of applications. This field of technology offers high potential profits. However, the bar to entry is high: those who do not take a professional approach will fall by the wayside. Knowing the possible pitfalls of patents and licences is crucial.

An Israeli research group is developing an apparatus for diagnosing Alzheimer's disease. It takes advantage of the fact that Alzheimer patients react differently to certain nerve stimuli than healthy people. When the patient is administered a low dose of a nerve stimulating agent on the retina, the pupil changes differently than in a healthy person. For measuring this effect, the apparatus has a camera that measures the pupil at regular intervals. The measurements are compared with standard data and from this it can be deduced whether the person being examined suffers from Alzheimer's disease.

The European Patent Office has rejected this patent application on the grounds that the invention protects a „diagnostic method for the human body". (T0143/04)

Patenting problems also arise with „reach-through claims": Bayer discovers that a novel mechanism of action can be used for drugs to treat cardiovascular diseases. This can be achieved by influencing a specific biochemical signalling pathway. It then applies for a European patent for the use of any compound that stimulates a specific enzyme (namely soluble guanylate cyclase). In the description Bayer gives a concrete example of such a compound and a method of finding other compounds with the same effect.

The European Patent Office rejects the claim on the grounds that it is far too broad. It must be restricted to the concrete example given in the application.

"Medicine is the most noble of the sciences."

Hippocrates of Kos (460 – approx. 377 BC)

Non-patentable “diagnostic Procedures”

As in other areas, computer support is becoming increasingly important in medicine. Technical measurements take place not only in the laboratory but also on the patient himself. Sensor measurements can be evaluated quickly and statistically reliably with software. This supports physicians in their work and contributes to treatment quality.
Patent law, however, reaches its borders when entering the field of diagnosis, therapy or surgery. European patent law excludes from patentability „methods for surgical or therapeutic treatment of the human or animal body and diagnostic methods which are carried out on the human or animal body“.
What is classified as a „method of diagnosis of the human body“? According to EPO case law, a diagnostic method has four phases:

i) Examination: collecting data on the human body.
ii) Comparison: comparing data with standard values.
iii) Detection of symptoms: finding a sig nificant difference from the standard values.
iv) Diagnosis: inferring potential pathologies from the difference.

If a method covers all four steps, it is considered a „diagnostic method on the human body“ and is excluded from patent protection.
The exclusion can be avoided if one of the steps is missing. However, it is not sufficient to simply hide one of the steps if it actually belongs to the invention. These cases have no one-size-fits-all solutions.

Develop your patent documents in a way that avoids non-patentable categories.

Avoid Inadmissible “Reach-Through” Claims

An invention must be described in the patent specification in such a way that a professional in the field can subsequently implement it. In certain cases it is sufficient to indicate a single way to implement the invention. In the field of biotechnology and pharmaceuticals, however, the effect of a particular molecule can rarely be generalized. A broad claim must therefore be supported by a sufficient number of different examples. This is the so-called disclosure requirement.

If the invention consists in defining a screening method using a specific molecule, this can result in a very broad claim. The molecules actually covered by the claim can only be identified when the screening procedure is carried out. The claim therefore only defines a test procedure or a molecular mechanism of action.

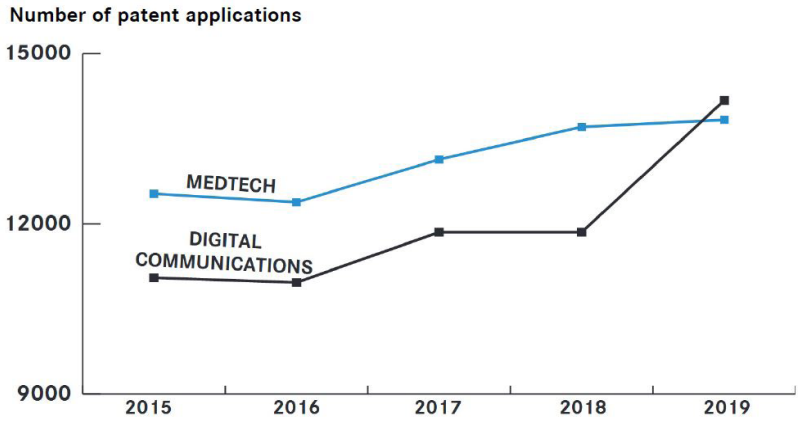
Such a claim is called a „reach-through claim“. It reaches through to as yet unknown molecules which can only be found in reality with the screening method. EPO case law does not allow such claims.

When filing broad claims, include as many examples as possible in the description.

Patentability of Medical Technology

Each patent application is classified in the International Patent Classification (IPC). Medical technology inventions belong to class A61 and its subclasses. For example: A61B „Diagnostics; surgery; identification“ or A61M „Devices for introducing or applying substances into or on the body“.
When the Office examines the invention for patentability, it searches the patent literature for identical or similar solutions. In doing so, it looks primarily in the medical technology class. But not only that: Often there are similar technical solutions also outside of medical technology and then these patents are also cited. The decisive factor for patentability in those cases is that the solution known outside of medical technology can only be used for medical applications with special, nonobvious adaptations.
In an application for a bone screw, the examiner cited a wood screw from 1894 against us. Even if there were technical similarities, the wood screw could certainly not have been implanted as a bone screw without adjustments.

In patent documents, emphasize the non-trivial adjustments needed for medical applications.



Growth of the two largest patent areas
over the past 5 years

Set up scientific cooperation for success

The ideas for new therapies and diagnoses often come from researchers in universities and physicians at hospitals. Even though universities are essentially charged with the task of conducting research in the public interest, they are also subject to certain economic pressures. They are therefore keen to monetize their research results through patents and licences.

The prerequisite for such a strategy is that the rights to the inventions belong to the institution and not to the scientist from the outset by way of a contract of employment. If the scientist overlooks this and grants rights in his or her own name, for example to a start-up, this will get the parties involved into trouble sooner or later.

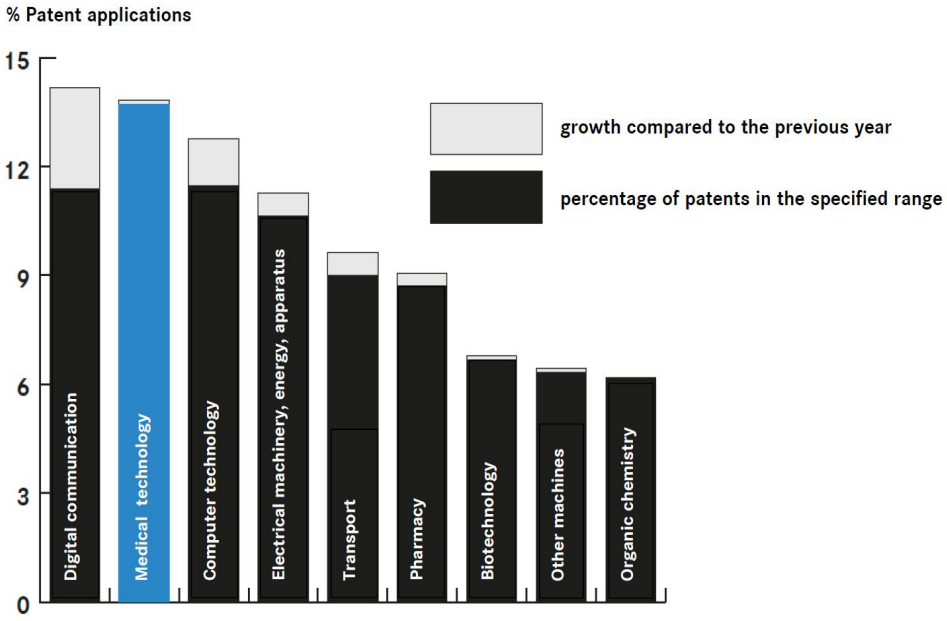
Having a renowned research institution on board is obviously effective in terms of advertising. However, it also brings with it restrictions on the rights of use. Universities insist that they can use the research results for further projects. They would therefore like to be the owner of the patent and grant the entrepreneur a licence for a specific field of application.

On the other hand, the company should be careful to ensure that it can influence the wording of the patent. It is in its interest that the licensed field of application is protected as well as possible.

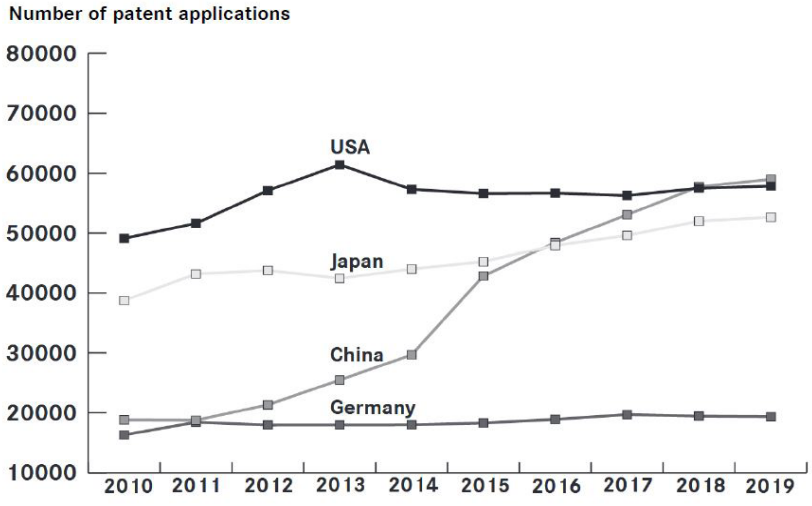
There are also various other aspects that must be kept in balance in a contract with a university, such as publication rights and confidentiality, obligations in the case of exclusivity of the licence and rights in the case of a simple licence, minimum use, etc.

Do not rely on standard contracts.

Patent applications 2019 in percent
by categories compared to the previous year



Patent applications in the four most active countries
over the past 10 years



Ask us

Stephan Kessler
I have been dealing with patent law issues in medical technology for all 10 years of my professional activity, first in an international medical company and later as a freelance patent attorney. I have had the opportunity to gain a lot of insight in this field working with scientists, technicians and official examiners. I am amazed by the amount of technical know-how needed to develop a new medical product: From materials science to medicine, materials processing, mechanics and (bio-) chemistry, everything is represented. I am excited when I see that a team solves complex problems with a simple and elegant approach.

How do I get a good patent license?

You cannot or do not always want to be the owner of the property rights. In these cases, a lot depends on the correct drafting of the licence agreements:

- If you would like to know how high an appropriate license fee could be in a specific case, we can provide you with reference cases.
- If you are looking for a high degree of exclusivity, we can suggest appropriate contractual parameters.
- If you are already preparing a patent application with the aim of granting licenses later, we can formulate the application document in such a way that it provides an optimal basis for licensing.

What do I need to do to obtain patent protection „at the frontier“?

Patents naturally become important in situations that lie in the future. It is important to anticipate possible difficulties and keep options open. We make sure that we write your patent for the future:

- We avoid surprises in the examination process by conducting intensive searches of the state of the art in advance.
- We base the patent specification on your objectives, but also build in delimitation options for other scenarios.
- We write ambitious claims, but prepare for the possibility that not everything gets through the examination proceedings („realistic catch-all positions“).

Keller & Partner Patentanwälte AG
Eigerstrasse 2
CH-3007 Bern
T +41 31 310 80 80

Bahnhofplatz 18
CH-8400 Winterthur
T +41 52 209 02 80

info@kppat.com
www.kppat.com

K&P Patentanwaltsges. mbH
Linprunstrasse 10
DE-80335 München
T +49 89 54 80 3737

info@kppat.com
www.kppat.com

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