Limitations on Patentability for Medical Devices (Part 2)

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Abstract

In the field of medicine and medical devices, patenting is restricted in the public interest by an exclusion from patentability for medical methods, i.e. diagnostic methods, therapeutic methods and surgical methods. Products, such as drugs and medical devices, by contrast, are patentable. In modern medical technology, however, the boundaries between medical device (hardware and software) and medical procedure are no longer sharply separable in every case. Part 1 of this article discusses the legal framework and the patentability exclusion for medical methods in a medical device context. Part 2 focusses on the patentability of medical devices as such. In a concluding section, we provide some "DOs" and "DON'Ts" regarding the patenting of medical devices and device-related methods.

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I. Introduction

In Part 1 of this article, the exclusion of medical methods from patentability in the patent acts of various countries, such as Switzerland and Germany, as well as in the European Patent Convention (EPC) are discussed. It is pointed out that the patentability exclusion is absolute and applies regardless of how innovative the method may be.

Further, different types of method claims are considered in Part 1 in more detail. While in some cases the patentability exclusion would necessarily apply, there are also methods that can be claimed without violating the patentability exclusion. This is the case where the method in question only concerns the technical operation of a medical device, without affecting its medical functionality. By way of example, methods for testing a battery or detecting malfunctions in a medical device are in principle patentable.

The patentability exclusion does explicitly not apply to products that are used in medical methods, be they drugs and their components, devices or computer programs or software (computer-implemented inventions).

At a first glance, one may accordingly assume that the patentability of medical devices would be unproblematic and not an issue as far as the patentability exclusion is concerned. While

this assumption is indeed true in many cases, the exclusion from patentability can still be relevant and therefore needs to be carefully considered.

In order to avoid misunderstandings, it should be noted that the term "medical device" as used in this article is not necessarily strictly identical to the definition in other, especially regulatory contexts. In practice, however, they can be considered as largely equivalent. Beyond the scope of this article are substances or compositions that are used in medical methods, such as drugs. Here, different provisions apply.

Note: In the interest of readability, detailed information on legal texts and legal bases is largely omitted. Main resources that may be used for a more detailed view are:

- Section G-II, Chapter 4.2 of the Guidelines for Examination in the European Patent Office (Edition March 2023);
- Chapter I.B.4 of the Case Law of the Boards of Appeal (10th edition, July 2022).

Further, we occasionally refer to particular decisions of the Boards of Appeal or the Enlarged Board of Appeal as the judicial instance in procedures before the European Patent Office. All decisions are accessible online in the Boards of Appeal decision database. [1]

Further, we refer to the "Guidelines for Examination in the European Patent Office" (generally referred to as "Guidelines", see link above), which are a core document published by the European Patent Office and define the established examination practice that should be followed by European patent examiners. [2]

In the following sections, we will distinguish between three groups of medical devices, which will be discussed separately. Group I concerns "uncritical" cases where the exclusion from patentability does not normally require special attention. Group II concerns inventions relating to (*per se* unpatentable) medical methods. The medical devices used in such methods are generally patentable, but require special care. Group III concerns cases where the exclusion of medical methods from patentability actually prevents the patenting of devices.

Finally, we derive some practical conclusions and recommendations for the patenting of medical devices.

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[1] Decisions are referred to with the respective case number, which is set in bold letters, beginning with "G" for the Enlarged Board of Appeal respectively a "T" for a Technical Board of Appeal, followed by a numerical code, e.g. **G1/04** or **T245/87**.

[2] References to the Guidelines are made by **"GL"**, followed by the respective section.

II. Group I: The uncritical cases

A first and in principle uncritical group are medical devices for which the *novel and inventive characteristics are directly represented by structural features of the device*. The meaning of "structural features" shall be illustrated by a number of examples [3].

1. Examples

- The medical device is a dental drill. The invention concerns a novel geometry of the cutting edges that produces particularly smooth surfaces and causes little vibration in use. A claim for the dental drill may be drafted in a straight forward manner, pretty much in the same way as it would be the case for a drill designed for cutting wood or steel.

- The medical device is an implantable cardiac pacemaker. The invention concerns a sheathing of the pacemaker housing. The sheathing significantly reduces the built-up of fibrotic tissue. A device claim for the cardiac pacemaker with the sheathing may be drafted pretty much in the same way as it would be the case for any other type of non-medical device.

- The medical device is a medical sonography system. The invention concerns a newly designed amplifier circuit for the transducer signals that results in an improved noise reduction. A claim for the sonography system (or potentially for the inventive amplifier circuit as such) is typically an uncritical device claim.

2. Relation to medical methods

Whilst patenting the medical device as such is generally uncritical in the examples discussed above, the following is noted:

- Regarding the dental drill example, a claim for a method of removing dental defects using the drill, e.g. at a speed that is particularly favourable in combination with the new geometry, would generally be regarded as surgical (and potentially also therapeutic) method and would accordingly fall under the patentability exclusion. If, however, it turned out that the novel dental drill surprisingly also had a useful application in machining ceramics in a non-medical context or for producing a dental implant in a dental laboratory, a method claim for this application would generally be possible.

- In the case of the pacemaker example, let's assume that the improved device requires special steps or modifications of known implantation procedures. Such an implantation procedure would fall under the patentability exclusion, because it would

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[3] Examples that are used in this article for illustrative purposes are generally fictive. In contrast, references to (European) case law concern "real cases".

generally be regarded as surgical method. On the other hand, any preparatory step, which as such does not involve the patient body, could be patentable.

- Regarding the medical sonography system, a method for capturing medical images that relies on the sonography system with the newly designed circuit is in principle patentable in addition to the sonography system. This may be surprising, but the problem of patentability exclusion is in fact less critical for diagnostic methods compared to therapeutic and surgical methods. In many cases, a patentability exclusion can be avoided by not claiming the steps which actually lead to the diagnosis. Those relevant steps, traditionally performed by a physician, are briefly outlined in the following. Pursuant to Enlarged Board of Appeal Decision **G1/04**, a method should only be considered a "diagnostic method" and accordingly be excluded from patentability under Art. 53 (c) EPC, if it includes – in combination – a series of steps, with the last step being a *medical decision phase* [4] respectively the medical diagnosis in a strict sense. Any preceding step or combination of steps that *does not include the medical decision phase*, such as the capturing of medical images, may be used as part of a medical diagnosis, but does not constitute an excluded diagnostic method (see Part 1 of this article, section IV.1). However, an automated method for the diagnosis of Arteriosklerosis in an early stage that relies on an AI-based evaluation of the high-quality images which are possible thanks to the new circuit and provides the diagnosis as output, would include the medical decision phase and would most likely fall under the patentability exclusion. Similarly, an X-ray imaging method is allowable, while a method that also includes the automated diagnoses of a bone fracture is not allowable.

III. Group II: Medical devices that are characterized by medical method steps

1. Functional claim features

When drafting device claims, it is common practice to formulate at least some features as so-called *functional features*, i.e. features that are defined in terms of their function during operation respectively in use, rather than in terms of the device strucutre. Often, the use of functional features results in a broader claim scope as compared to a merely structural "nuts and bolts" approach, and can further be favourable in view of clarity and conciseness. A simple example [5] is a "terminal position detecting means", which may, e.g., be realized with an electro-mechanical limit switch, but also with a photoelectric cell, a strain gauge sensor, etc.. While often not recognized as such, also frequently used technical terms such as "low

[4] i.e. the assignment to a clinical picture respectively the diagnosis in a strict sense, such as "Arteriosklerose".

[5] see **GL F-IV, 6.5**

pass filter", "power supply" or "reduction gear" refer to a functional definition of the respective device and may generally be structurally realized in many different ways.

Functional claim features are often used in claim drafting, e.g., for circuitry (where it is often tedious and potentially meaningless to specify in detail the types of components and/or their interconnection), as well as for features that are implemented in the form of program code in the context of computer-implemented inventions (CII). Here, functional features may be the only option available. Also, complex mechanical interactions are often best described in a functional rather than a structural language.

The admissibility of functional claim features is in principle explicitly acknowledged by the European Patent Office and other Patent Offices. According to the Guidelines, a functional feature is acceptable

> *"provided that a skilled person would have no difficulty in providing some means of performing this function without exercising inventive skill"* [6].

Depending on the circumstances, a single specific example in the application may be sufficient.

It is noted that (permissible) functional features are to be distinguished from (in most cases impermissibly) "attempting to define the invention by a result to be achieved." By way of example, it is established that a claim to a catheter "with reduced risk of internal injuries" would not be allowed. In practice, however, even technical claim features which the authors consider to be clearly allowable are frequently objected to as allegedly being directed towards a result to be achieved.

2. Patenting medical steps via functional device features

While the usefulness of functional device features is general and not directly linked to inventions concerning medical devices, they are particularly relevant here as discussed in the following. In fact, they are often the most suitable – if not the only available – option. Consequently, also the frequent objections raised by examiners against such features are particularly problematic in this field.

The principle of patenting medical steps via functional device features is in the following illustrated by a number of examples.

- The invention concerns an improved algorithm for closed loop control of continuous insulin infusion with glucose sensor feedback. While the control method is excluded from patentability as a therapeutic and surgical method [7], a system that is configured

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6 see **GL, F-IV, 2.1**

7 see Part 1, section IV.2.1 of this article

to execute the control method is patentable. The claimed system may include a continuous glucose sensor, an insulin infusion pump and a control device. The control device may be *configured to receive glucose-data from the sensor, to process such data in accordance with the innovative control algorithm and to generate corresponding control commands for the insulin infusion pump*.

- The invention concerns the implementation of incisions in the corneal tissue with an ophthalmological surgical laser device according to a particular novel cut pattern in order to treat a refractive error. While the method for implementing the tissue cuts according to the novel cut pattern is excluded from patentability as being both a therapeutic and a surgical method, a system with an ophthalmological surgical laser device and a control device coupled thereto *that is configured to control the laser device for implementing the tissue cuts according to the novel cut pattern* is patentable.

- The invention concerns the release of muscle cramps by applying a combination of heat and electrical stimuli according to a novel and beneficial pattern. While a method for the treatment of muscle cramps is excluded from patentability as therapeutic method, a *device that is configured to apply heat and electric stimuli according to the novel pattern* is patentable.

The expression "configured to" – and a number of alternative wordings – indicate that the device is designed in such a way that the respective functions can be performed during operation of the device.

For a device being configured to execute a particular method, no link to particular structural features of the device is required in many cases. It is established practice that some or all features may also be realized by way of software or firmware code that is executed, e.g., by a microprocessor or microcomputer or that run on a *per se* general-purpose computer such as a PC. Typically, this would be the case for all examples mentioned above.

It is in any case essential, however, that the claimed device with all claim features, including especially the functional claim features that are directed towards the medical method steps, can be manufactured [8] respectively realized *without executing any steps that would fall under the patentability exclusion*. In other words, all claim features must be inherent features of the claimed device as such and can accordingly be identified, e.g., by way of reverse engineering, bench tests, and the like.

3. Device-body interaction

When patenting medical devices, special attention should be paid to interactions between the medical device and the patient. For the examples of a dental drill or the cardiac pace-

[8] The manufacture of the device in this context may also include the loading of software code.

maker with protective housing sheathing as discussed in Section II.1 above, it may be possible to draft claims that do not comprise any reference to the patient. In many other cases, however, this is not possible.

For the example of implementing incisions on the corneal tissue with an ophthalmological surgical laser device as discussed in Section III.2 above, the positioning and arrangement of the incisions would generally require a specification in relation to the patient's eye, for example in relation to the anterior corneal surface. In another example, a meaningful claim for a dental implant may require a reference to the jawbone. The question of references to the patient's body has been the subject of a number of Board of Appeal decisions. It is now widely accepted that such references to the patient's body are in principle permissible.

For example, decision **T1695/07** concerned claims directed towards a process and an apparatus for monitoring the rate of blood flow in a shunt. All method claims were considered as being excluded from patentability. However, this was not the case for the apparatus claims, which were found to be allowable in principle. It was explicitly held that that *functional claim features that are defined in relation to the body of the patient* were allowable. Specifically, Reason 17.2 of the decision states (emphasis added):

> *"The fact that some features of the claimed apparatus are functionally defined in relation to the body of the patient (e.g. the shunt) does not itself transform the apparatus claim into a method claim (**T712/93**, Reasons Point 3). It is true that the operation of the apparatus requires an intervention on the patient's body and involves certain steps of a surgical character (which is the case for many medical devices). This, however, does not except the claimed apparatus from patentability under Article 53(c) EPC."*

The earlier decision **T712/93** referred to in the cited passage concerned an "Apparatus for use as the socket portion of a prosthetic ball and socket joint" and also confirmed patentability of the apparatus.

Case **T1798/08** concerned a visual prosthesis.[9] The claim under discussion included the functional features (emphasis added) "*(wherein) the secondary coil and the decoding and demultiplexing circuit block are suitable to be located extra-ocular on the body of the user outside a wall of the sclera*" and "*the secondary coil is suitable to be located implanted in the eye behind the iris*." It was specifically stated that the expression "suitable for" did not refer to a surgical intervention, but merely defined that the visual prosthesis was *designed in a manner that it can be located* at various locations in the patient's body.

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9 The figure below is taken from the application WO9945870A1 / EP1061874A1 to which **T1798/08** relates.

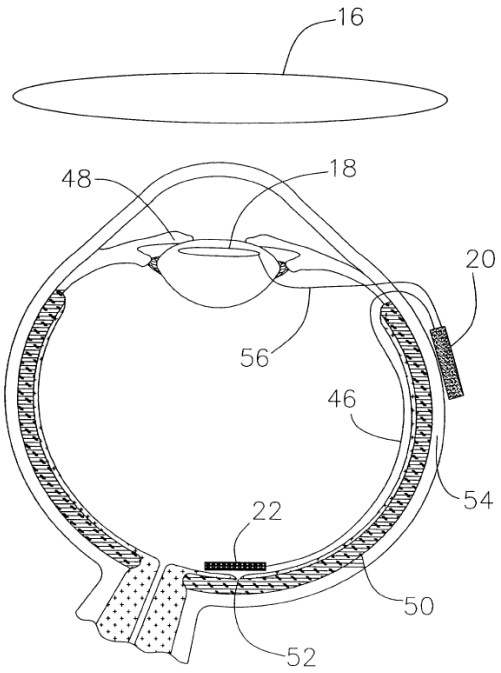

Fig. 5

While references to the patient's body and also to medical method steps in a medical device are accordingly not *per se* excluded but allowable under certain circumstances, it is again emphasized that the claim features must define the device "as such", i.e., as it is provided to the medical professional, e.g. a surgeon. *More specifically, the claim must be directed towards the device before any step falling under the patentability exclusion is carried out.* For example, a claim directed towards "a dental implant having an anchoring section that is *configured to be anchored in a patient's jawbone*" is acceptable. In contrast, a claim directed towards "a dental implant having an anchoring section that *is anchored in a patient's jawbone"* would most likely be objected to. The reason is that the latter formulation implies that the surgical step of anchoring in the jawbone has to be carried out in order to obtain the claimed configuration.

IV. Medical devices excluded from patentability

In Section III.3 above, it is emphasized that all features of the claimed device must be present before any steps falling under the patentability exclusion, in particular any steps considered as surgical, are carried out.

In many cases, this can be achieved by way of thorough claim drafting. An example is the dental implant mentioned above. With expressions such as "configured to" it can be clarified that a claim feature is an inherent feature of the claimed device and does not rely on the execution of any steps that would cause a patentability exclusion.

A landmark decision on the patentability exclusion for medical devices is **T775/97**. The invention concerned a bilateral intra-aortic bypass graft. The claim set under discussion comprised a claim for "A bilateral surgical bypass graft…" which was, in the claimed form, *obtained only in the patient's body in a surgical procedure* by disposing two tubes into a body passageway and subsequently expanding them. The summary of the decision states (emphasis added):

> *No European patent can be granted with claims directed to a new and even possibly inventive way of using materials or devices, in particular endoprotheses, involving a treatment by surgery. This is equally true for product claims defined by a construction which is only arrived at in the human or animal body following a surgical method step.*

This approach was confirmed by subsequent decisions and is also in line with earlier decisions.

Two further relevant decisions are (earlier) **T712/93** (see Section III.3 above) and (subsequent) **T1407/08**. The latter concerned an "Aortic graft for treatment of abdominal aortic aneurysms". A claim under discussion defined the graft by a number of features of the graft itself, but also its assembly in the patient's aorta. The Board found (Reasons 4., emphasis added):

> *"… even if the final aortic graft is normally obtained after assembly in the body of the patient during surgery, the surgical steps of introducing the different parts or portions of the graft into the body and assembling them while in the body do not fall under the scope of the claim and therefore cannot lead to an objection under Article 53(c) EPC."*

In particular, the claimed graft was as such *defined by the functional relationship among the components which were already present prior to surgery*.

A more recent decision that deals with extending the patentability exclusion for medical methods to medical devices and refused patentability is **T1731/12**.

The claims under discussion in **T1731/12** concerned a "Device for the desynchronization of activity of pathologically active brain areas comprising means for stimulating brain regions". [10] Such devices are used in the treatment of neurological or psychiatric diseases. The claimed device should comprise at least two electrodes and control means for driving the electrodes to emit stimuli. The further claim features concerned the control and in particular the timing

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10 The figure below is taken from patent application US2001/0051819A1 which is directed towards the same type of device.

of the signals provided to the electrodes. The control means could in particular be realized by a computer with the corresponding program code to implement the claimed functionality. At a first glance, the claims look like typical medical device claims with a number of functional claim features as discussed in Section III.2 above. Therefore, the decision surprised and also irritated many patent practitioners working in the field of medical devices.

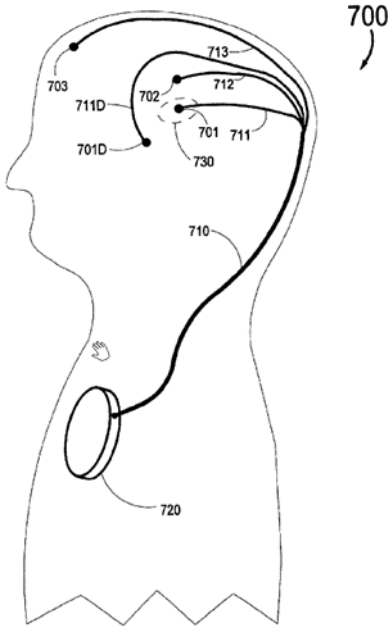

FIG. 22

In the case at hand, the Board concluded, based on a number of passages in the description, that the relevant (functional) claim features of the device did not concern the device *per se*. Instead, they were *obtained only during implantation,* where an optimal positioning of the electrodes was determined, and afterwards when the stimulation parameters were adjusted and in particular the stimuli were increased until the desired effect was reached. The Board explicitly referred to the previously discussed decisions **T1407/08** and **T712/93** which in each case affirmed patentability of the device in question. The principle that medical devices which may be used in an as such excluded medical method can be patentable was explicitly confirmed. The underlying pre-condition of the earlier cases, however, that all claim features have to be realized by the device as such was not fulfilled in the Board's view.

The patentee tried to counter this view and argued that the claimed device actually was present with all its features prior to the implantation. Particularly, the device comprised a computer that stored data of the disease pattern. In combination with the knowledge of the skilled person, such data could serve as initial values for the frequency and intensity of the stimuli. It was accordingly *not mandatory to determine them during calibration* (i. e. after implantation). Consequently, the claimed device was *fully defined and existent already prior to implantation*. These arguments however, were not found convincing.

Further considering the fact that according to **G1/07** a single surgical step is sufficient for a claim to violate Art. 53(c) EPC, the Headnote of **T1731/12** states:

> *Eine Vorrichtung, die durch ein Merkmal definiert ist, das nur durch einen chirurgischen oder therapeutischen Schritt erzeugt werden kann, ist nach Artikel 53(c) EPÜ von der Patentierung ausgenommen (in Fortführung von **T 775/97**).*
>
> *[A device defined by a feature which can only be produced by a surgical or therapeutic step is excluded from patentability under Article 53(c) EPC (in continuation of **T 775/97**).]*

To give another (fictive) example: In Section II.1 above, the case of a cardiac pacemaker with a particular housing sheathing was discussed. The sheathing, when applied as part of the manufacturing process of the cardiac pacemaker, clearly concerns the device *per se* and is therefore uncritical in the discussed context. Now, however, another scenario is assumed in which a cardiac pacemaker is placed in a bag designed and made from a material such that a built-up of fibrotic tissue is prevented. It is further assumed that placing the pacemaker in the bag is done during the implantation procedure, e.g. subsequent to positioning the stimulation electrodes. Now, the patentability exclusion trap would be likely to snap. What still may be possible is a claim for a kit that includes both the cardiac pacemaker and the bag that is configured to be used in the described way.

V. Patenting of medical devices: Some recommendations

In this section, some practical guidance regarding the patenting of medical devices and medical device-related methods especially in Europe is provided. It is noted, however, that each particular case calls for a thorough individual consideration. The following is therefore to be understood as a checklist of points that should be considered.

1. DOs

- The claims should be drafted in a way that makes it clear that all claim features (structural, functional and/or potentially implemented by software/firmware code) are already present before any surgical and/or therapeutic step is carried out.
- If some features are typically realized in a surgical step (as it was the case for the aortic graft in **T1407/08**), it should be described how they *can be realized* in a purely technical setup without involvement of a patient's body. This is based on the fact that the patentability exclusion only applies, if a surgical and/or therapeutic step is *necessarily required*. Particular care should be taken in this regard to features such as the

positioning of elements as well as the adjustment or tuning of parameters to achieve the intended effect.

- If some fine tuning or adjustment of parameters is typically done during and/or after a surgical and/or therapeutic step, it should be described how initial values can be set, e.g., as starting points, prior to any surgical and/or therapeutic step. It must be clear that the claimed functionality is already established with such initial values, even if not optimal.

- Favorably, it is described how the claimed device can be put into operation and that the presence of all claim features can be verified in a *purely technical setup*, e.g., on the laboratory bench. Such information may, e.g., be presented in the application in the context of a functional test.

- The focus of the patent application should lie on the technical aspects of the device. As far as surgical and/or therapeutic aspects are addressed, it may be helpful to clearly identify them as background information respectively optional (e.g. for the fine-tuning of operational parameters), if included at all.

- If the invention is in principle a technical method or algorithm carried out by a medical device (e.g. related to device control, fault detection, or power management) and is unrelated to the medical functionality, method claims are allowable and may well be of value. However, it is recommended in such cases to additionally claim the medical device that is configured to execute the method, and not to rely exclusively on the method claims.

2. DON'Ts

- The claims must not include claim features that are realized only in a medical, especially surgical step.

- No surgical or therapeutic steps must be presented as being essential for realizing the invention. This applies not only to the claims, but also to the description.

- Especially for functional device features and features that are described in relation to the patient's body it is crucial not to confuse such features with their resulting effect during the medical application. Such aspects should be distinguished from each other in a clear-cut way.