Ausgabe IV / Juni 2022

Swiss Engineering STV
Fachgruppe Medizintechnik
Newsletter

Beschränkungen in der Patentierbarkeit von Medizinprodukten

(Teil 1)

SWISS ENGINEERING
FACHGRUPPEMEDIZINTECHNIK

Inhalt

Botschaft des Präsidenten

Liebe Kolleginnen und Kollegen,

wie Sie wahrscheinlich schon bemerkt haben, wurde unsere Fachgruppe in « Medizintechnik » umbenannt. Wie von der Generalversammlung im November 2021 beschlossen, wird sich die Fachgruppe hauptsächlich auf Medizintechnik und Biomedical Engineering konzentrieren. Um unsere Aktivitäten sichtbarer zu machen, wurde die Umbenennung der Fachgruppe für notwendig erachtet.

In dieser Ausgabe unseres Newsletters finden Sie einen Artikel von Dr. Axel Remde, Patenten-Anwalt und Vorstandsmitglied, über Beschränkungen in der Patentierbarkeit von Medical Devices. Ich wünsche Ihnen viel Spaß bei der Lektüre und freue mich darauf, Sie bei unseren nächsten Veranstaltungen begrüssen zu dürfen.

Herzliche Grüsse,

Valentin Herbez

Info aus dem Vorstand

Nach der Generalversammlung 2021 und der Wahl von Simon Burri, hat der Vorstand die Ämter wie folgt aufgeteilt: Dr. Axel Remde übernimmt das Vizepräsidium und Simon Burri wird neu Academic – Industry Liaison eingesetzt. Valentin Herbez behält das Präsidium und Frank Zeugin die Finanzen.

Veranstaltungen

Folgende Veranstaltungen sind geplant:

Datum	Thema	Wo
05. Okt.	Bioprinting : Besichtigung der Firma REGENHU https://www.regenhu.com	Villaz-St-Pierre
30. Nov.	Generalversammlung 2022	Bern

Rückblick auf vergangene Veranstaltungen

Generalversammlung 2021

Am Mittwoch, den 24. November 2021 fand die Generalversammlung unserer Fachgruppe in Bern statt.

Als Keynote Speaker hat Bernhard Bichsel einen spannenden Vortrag zum Thema „Die neue Medizinprodukte Regulierung “ gehalten.

Bernhard Bichsel, Executive MBA HSG, Dipl. El.-Ing. FH/STV, ist Geschäftsleiter der ISS AG (Integrated Scientific Services) in Biel und ehemaliger Leiter der Abteilung Medizinprodukte bei Swissmedic.

Nach dem offiziellen Teil konnten alle Teilnehmer einen Networking Apéro geniessen.

Biomedical Engineering Day 2022 der Universität Bern

Am 20. Mai fand zum 13ten mal der Annual Biomedical Engineering Day der Universität Bern statt – nach einer pandemiebedingten Online-Durchführung im Vorjahr nun wieder als Präsenzveranstaltung am Inselspital.

Nach Informationen zum Studium Master of Science in Biomedical Engineering, als von der Universität Bern und der Berner Fachhochschule (BFH) gemeinsam angebotenem Masterstudiengang sowie das ARTORG Center for Biomedical Engineering Research und das im Herbst 2021 gegründete Innovation Office der Universität Bern, stellten sich verschiedene Schweizer Medizintechnik-Firmen und aktuelle Projekte in Kurzreferaten vor.

Den Mittel- und Höhepunkt der Veranstaltung bildete die Verleihung verschiedener Awards und zwar in den Bereichen Best Master Thesis Abstract, Best Master's Student, Best Master Thesis sowie Best PhD Thesis.

Der Best Master Thesis Award wurde dabei wie in der Vergangenheit in den beiden Kategorien Innovation und Basic Science vergeben und von Swiss Engineering gesponsert. Preisträger in der Kategorie Innovation ist Herr Aurélien Dorn mit seiner Arbeit "COPD-on-Chip: Validation and technical development of a continuous flow inhalation chamber". Sieger in der Kategorie Basic Science ist Herr Remo Muri, mit seiner Arbeit "Personalized prediction of the outcome of percutaneous coronary interventions".

Swiss Engineering und die Fachgruppe Medizintechnik gratulieren allen Preisträgern und natürlich insgesamt allen Absolventen des Studiums zu ihrem grossen Erfolg.

Den Abschluss des Hauptteils bildete die für Ingenieure nicht allzu häufige und sehr spannende Möglichkeit, die Implantation eines Herzschrittmachers an der Universitätsklinik für Kardiologie des Inselspitals durch PD Dr. med. Dr. phil. Andreas Häberlin in einer Life-Übertragung mitzuverfolgen. Dabei wurden alle Schritte von Dr. Häberlin sowie seinem Kollegen Dr. med. Jens Seiler, der am BME Day vor Ort war, unmittelbar kommentiert und erläutert.

Anschliessend folgte ein Lunch und reichlich Gelegenheit, die Ausstellungsstände von Medizintechnik-Unternehmen sowie von Forschungsgruppen des ARTORG Center zu besuchen und dabei ins Gespräch zu kommen.

Dr. Axel Remde, Vorstand FG MT

Fachbeiträge

In diesem Teil wollen wir innovative Forschungs- oder Industrieprojekte im Bereich der Medizintechnik vorstellen. Als Mitglied der Fachgruppe haben Sie die Möglichkeit, ebenfalls ein Thema zu präsentieren; zögern Sie nicht, sich bei Interesse an ein Vorstandsmitglied zu wenden.

Medizintechnik in der Schweiz: Zur Lage nach dem Abbruch der Verhandlungen über das institutionalisierten Rahmenabkommen (InstA)

Politische Fragen gehören für die meisten Ingenieure und Naturwissenschaftler nicht unbedingt zu den spannendsten Themen, doch können sie für ihre Arbeit eine nicht zu unterschätzende Bedeutung haben. Ganz sicher ist dies in der regulierten Branche der Medizintechnik der Fall: Der Abbruch der Verhandlungen über das institutionalisierten Rahmenabkommen (InstA) mit der EU ändert die Bedingungen in der Schweiz grundlegend: Dies gilt sowohl für die Versorgung der Schweizer Bevölkerung mit medizintechnischen Produkten aus dem Ausland als auch deren Export aus der Schweiz.

Mindestens im ersten Punkt zeichnet sich eine gewisse Entspannung ab: Die Motion 20.3211 von Ständerat Damian Müller «Für mehr Handlungsspielraum bei der Beschaffung Medizinprodukten zur Versorgung der Schweizer Bevölkerung» wurde am 30. Mai 2022 im Ständerat angenommen, nachdem bereits am 11. Mai 2022 der Nationalrat die inhaltliche gleichlautende Motion 20.3370 «Zulassung von Medizinprodukten nach aussereuropäischen Regulierungssystemen» von Nationalrat Albert Rösti gutgeheissen hatte. (weitere Informationen etwa unter 20.3370 Motion (Albert Rösti) | Swiss Medtech (swiss-medtech.ch) und 20.3211 Motion (Damian Müller) | Swiss Medtech (swiss-medtech.ch)).

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Unabhängig davon, wie es hier konkret weitergeht, steht die exportorientierte Schweizer Medizintechnik-Branche vor grossen Herausforderungen. Näher erläutert dies unser Fachgruppen-Mitglied Bernhard Bichsel von der ISS AG (Integrated Scientific Services) in Ausgabe Nr. 05, Mai 2022 unserer Zeitschrift STZ in einem Artikel unter dem Titel "Was der Bruch mit Europa für die Medizintechnik bedeutet".

Dr. Axel Remde, Vorstand FG MT

Beschränkungen in der Patentierbarkeit von Medizinprodukten (Teil 1)

Axel **Remde**, Christian **Ebner**, Alfred **Köpf** [1]

Zusammenfassung

Im Gebiet der Medizin und der Medizinprodukte wird die Patentierbarkeit von Erfindungen im öffentlichen Interesse, durch einen Ausschluss von der Patentierbarkeit für medizinische Verfahren eingeschränkt. Produkte, wie Arzneimittel und Medizinprodukte, sind dagegen patentierbar. Der Umfang und die Grenzen des Patentierungsausschlusses wurden und werden noch immer breit diskutiert. Dieser Artikel stellt den rechtlichen Rahmen und seine Anwendung im Zusammenhang mit dem Europäischen Patentübereinkommen vor und gibt verschiedene Beispiele, in denen ein Patentschutz möglich bzw. nicht möglich ist, einschließlich "Grauzonen". Dieser erste Teil des Artikels konzentriert sich auf die Grundlagen und erörtert insbesondere den Ausschluss der Patentierbarkeit von medizinischen Verfahren im Zusammenhang mit Medizinprodukten. Ein anschließender zweiter Teil wird sich mit den Auswirkungen auf die Patentierung von Medizinprodukten als solche befassen.

Patentability Limitations for Medical Devices (Part 1)

Abstract

In the field of medicine and medical devices, patenting is restricted in the public interest by an exclusion from patentability for medical methods. Products, such as drugs and medical devices, by contrast, shall be patentable. The scope and limitation of patentability exclusion have been and still are widely discussed. This article presents the legal framework and its application under the European Patent Convention and provides various examples where patent protection is, respectively is not possible, including "grey areas". This first part of the article focusses on the basics and specifically discusses the patentability exclusion for medical methods in the device context. A subsequent second part will focus on the implications for the patenting of medical devices as such.

Introduction

In highly innovative and competitive fields, gaining some monopoly for the exploitation of new developments by way of patent protection is, strongly desirable and may in fact be crucial for a complete business case. This holds true for large companies in view of the required return of investment, but also – maybe to an even greater extent – for small companies and startups who need to attract investors. In the medical filed, such an innovative and competitive environment is generally given, be it with respect to the development of new drugs or medical devices and services.

As it comes to patenting inventions in the medical field, however, particular provisions and limitations apply, which, if not properly taken into account right from the beginning, may result in a severe restriction of the obtainable scope of protection and may in the worst case even render patent protection impossible.

In a two-parted article, we review such restrictions with particular focus on the European Patent Convention. In the present first part, we start with a brief review of the background and the rationale for such restrictions, as well as the situation in a number of countries. Next, we discuss two general categories

[1] Dr.-Ing. Axel **Remde**, Dr. sc. ETH Christian **Ebner** and Dr. sc. nat. ETH Alfred **Köpf** are European and Swiss Patent Attorneys at Rentsch Partner Ltd. | Kirchenweg 8 | 8008 Zurich | T +41 44 225 70 70 | www.rentschpartner.ch

of matter for which patent protection may be obtained, namely methods on the one side and products on the other side. An understanding of the difference between the categories is important, since it has direct implications on patentability restrictions. On this basis, different explicit patentability exclusions are discussed in more detail.

In the second part, we will look into patenting of medical devices in more detail. Specifically, we will explore under what circumstances the patentability exclusions are generally critical. We will present a typical approach that may be followed for successfully patenting inventions in the field of medical devices in such cases. Further, we will discuss cases where a patentability exclusion may apply nonetheless.

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 2022);
- Chapter I.B.4 of the Case Law of the Boards of Appeal (9th edition, July 2019).

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.[2]

It is further noted that the drafting of patent applications is – for good reasons – generally the job of qualified professionals, in particular patent attorneys. However, in the authors' opinion, it is helpful and desirable that practitioners working in the medical device development have a basic understanding of the patentability limitations as it comes to patenting inventions in this field.

Background

Patents are issued in order to reward inventors with a temporally restricted monopoly for disclosing their inventions, such that others may use these newly developed insights for further advancing the state of the art. While it is in most fields unproblematic and appropriate to reward a specific party with such limited exclusivity, it is also largely accepted that ethical considerations should prevail over economic interests in certain areas.

One of these area is the field of medical technology. It is widely accepted in most societies that physicians should not have to worry about patent infringement when treating their patients. Further, physicians should be free to choose the most suitable method to diagnose and treat patients. This should apply irrespective of existing intellectual property rights.

Pursuant to the European Patent Convention (EPC[3]), claims directed to methods for treatment by surgery or therapy, as well as diagnostic methods practiced on the human or animal body are *per se* excluded from patentability by Art. 53(c) EPC and no European patent may be granted for such a method:

> *"European patents shall not be granted in respect of methods for treatment of the human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body, …"*

[2] 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**.

[3] Convention on the Grant of European Patents (European Patent Convention, EPC). Reference to the EPC are generally made with respect to the revised Convention or "EPC 2000.

This holds true regardless of how innovative or "inventive" the method may be. The same applies to the national Patent Acts of many countries, for example, among many others, Switzerland and Germany.[4,5]

US patent law, for example, follows a different approach to achieve the same goal. Specifically, US patent law does not recognize such limitation of patentability. Patents claiming medical methods may well be granted and a physician may indeed infringe such patents when treating patients. However, physicians are excluded by law from liability.[6]

Methods and products

While things are a bit more complicated in detail, two basic types of subject matter may be distinguished that can be patented and towards which claims can be directed: Namely, products on the one side and activities on the other side.[7] Products include everything that is made of matter and is in principle tangible; be it as volatile as a gas or as massive as a tank, be it as small as a bacterium or as big as a rocket. Product claims may for example be directed towards substances or compositions, such as a chemical compound or an alloy, as well as technical products like a toy, a box, a sensor, a motor, a drilling machine, a vessel or a skyscraper, as well as their components and subunits. Claims directed towards activates may for example be directed towards a manufacturing process for a compound, a method for applying an adhesive, a method for controlling a motor, or towards a particular application respectively use of a compound. For practical purposes, claims directed towards activities are referred to as "method claims". In many cases, they can be thought of as an algorithm.

In the medical field, it is as counterpart to the – at least in principle – widely accepted patentability exclusion for medical methods[8], equally accepted that medical products should eligible for patent protection, as also codified in the EPC. As a whole, Art. 53(c) EPC reads as follows (emphasizes added):

> *"European patents shall not be granted in respect of methods for treatment of the human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods."*

While substances and compositions for use in medical methods are specifically mentioned here for the sake of clarification, it is directly clear from the wording that generally all kinds of products that are used in medical methods should be patentable.

Since "medical devices" are undoubtedly products in the above-given meaning, it may be asked why the patentability exclusion for medical methods should be of any relevance for medical devices and their patent protection. The patentability of medical devices is generally unchallenged and even explicitly confirmed.[9]

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[4] Art. 2 para. 2 lit. a of the Swiss Patent Act.

[5] § 2a para. 1 no. 2 of the German Patent Act.

[6] 35 U.S.C § 287 bars a medical procedure patent owner from enforcing the patent, by obtaining an injunction, monetary damages, and attorney fees, against a medical practitioner and a related health care entity based on the medical practitioner's performance of "a medical activity" (35 U.S.C. § 287(c)(1)).

[7] See also "Guidelines for Examination in the European Patent Office", Edition March 2021, F-IV,3.1.

[8] The term "medical methods" is commonly used as collective term for methods that are excluded from patentability pursuant Art. 53(c) EPC and/or equivalent national law.

[9] Guidelines for Examination in the European Patent Office, Edition March 2021, G-II, 4.2.1.

> *"Claims to medical devices, computer programs and storage media which comprise subject-matter corresponding to that of a method for treatment of the human or animal body by surgery or therapy or to that of a diagnostic method practised on the human or animal body are not to be objected to under Art. 53(c), because only method claims may fall under the exception of Art. 53(c)."*

Nevertheless - and surprisingly at first sight - there are a number of situations in which patentability is limited or even appears impossible, even though the invention in question concerns a medical device respectively its operation.

The patentability exclusion for medical methods

The interpretation of Art. 53(c) EPC, in particular regarding the scope and limitations of the before-mentioned patentability exclusion pursuant to the EPC and other legislations have been - and to some extent still are - widely discussed. Besides, they are still the subject of debate, and resulted, in a number of decision of the Enlarged Board of Appeal of the European Patent Office (EPO) as ultimate authority on the interpretation of the EPC. While a detail review of this subject goes far beyond the scope of the present article, it seems crucial to understand the basic principle as background for what follows. It is important to keep in mind that this background section only refers to claims related to methods as explained before, and to products.

Before looking at the types of methods as mentioned in Art. 53(c) EPC (namely treatment by surgery; treatment by therapy; diagnostic methods), the following general points are noted:

First, the patentability exclusion only refers to methods that are executed on the living body. Consequently, it does not concern procedures carried out on a corpse or parts thereof, e.g. an organ removal in context of a transplantation. Similarly, it does not concern, e.g., the treatment of blood for storage in a blood bank or the in vitro testing of blood samples. In fact, Art. 53(c) EPC is generally understood in the sense that the (living) body must necessarily be present for carrying out a method to potentially cause a patentability exclusion.

Second, Art. 53(c) EPC defines three separate alternative exclusions. To result in an exclusion form patentability, it is sufficient that the method in question falls under either of them. For example, the treatment of a disease by taking a medicine orally is excluded as treatment by therapy, even though it is not surgical (nor a diagnostic method). Also, a method for hair removal may in principle be excluded as surgical method, even if it serves exclusively a cosmetic purpose.

In the following, the three types of methods are reviewed in more detail.

Diagnostic Methods

Regarding diagnostic methods, the applicable basic approach was formulated in Enlarged Board of Appeal decision **G1/04**, which gives the expression "diagnostic methods" a rather narrow interpretation. Pursuant to this decision, a claim could be considered to be directed towards a diagnostic method within the meaning of Art. 53(c) EPC and accordingly excluded from patentability only if it included all of:

(i) the examination phase, involving the collection of data,
(ii) the comparison of these data with standard values,
(iii) the finding of any significant deviation, i.e. a symptom, during the comparison,

(iv) the attribution of the deviation to a particular clinical picture, i.e. the deductive medical or veterinary decision phase (diagnosis for curative purposes *stricto sensu*).

If one or more of these steps is missing respectively not present in the claimed method, the method is not excluded from patentability. In such case, the method in question may be, e.g., a method of data acquisition or data processing that could be used in a diagnostic method. It would not fall under the patentability exclusion.

Further, the expression "practised on the human or animal body" in Art. 53(c) EPC implies that all of the four mentioned steps that are of "technical nature" must be practiced on the body, i.e. including some interaction with the body and accordingly requiring its physical presence (without, however, specifying any particular type or intensity of such interaction).

Further, step (iv) is considered as purely intellectual exercise and accordingly of non-technical nature, leaving steps (i) – (iii) for consideration. Among those steps, all that are of technical nature (in contrast to a mental exercise) need to be practiced on the body to qualify for a patentability exclusion. In practice, however, steps (ii) and (iii) are generally of non-technical nature and not practiced on the body. In typical practical cases, step (i) is therefore decisive.

The assessment principle as outlined above is in the following illustrated with some examples:

- A method for cancer diagnosis that is carried out *in vitro*, using a tissue sample, should not be excluded from patentability as diagnostic method since it is, including step (i), not practiced on the body.
- A method for determining and displaying a physiological parameter respectively body parameter, e.g. the body weight, body temperature or a blood glucose level, should not be excluded from patentability as diagnostic method, since it is, while useful and potentially required for a diagnosis, not a diagnostic method with all of steps (i) to (iv).
- A medical imaging method or a method for processing medical imaging data should also not be excluded from patentability as diagnostic method for similar reasons.
- A method for the diagnosis of hearing loss, including all steps from applying acoustic test signals to the ear and recording the patient's perception (step (i)) to the indication of the diagnosis (step (iv)) should be considered as diagnostic method and accordingly excluded form patentability.

Particularly with respect to the 2nd and 3rd example, it is noted that claims directed towards such methods may be objected nevertheless under Art. 53(c) as surgical methods, as discussed further below.

Treatment by therapy, treatment by surgery

For a diagnostic method respectively a method used in diagnosis, all of the before-discussed steps (i) to (iv) need to be present in order to even consider a patentability exclusion. As far as diagnostic methods are concerned, Art. 53(c) EPC is accordingly to be interpreted narrowly.

To qualify as treatment by therapy or surgery and thus causing a patentability exclusion, in contrast, a single therapeutic or surgical step in a claimed multi-step method will result in a patentability exclusion under Art. 53(c) EPC, as held by Enlarged Board of Appeal decision **G1/04** and confirmed by subsequent decision **G1/07**.

Treatment by therapy

The expression "treatment by therapy" is generally understood in its plain meaning, with therapy relating to the treatment of a disease in general or to a curative treatment in the narrow sense, as well as the alleviation of the symptoms of pain and suffering, and also encompassing prophylaxis.

Therapy however, has to be distinguished from purely cosmetically methods that serve an esthetic purpose, as well as from performance enhancement methods. Both kinds of methods may generally be patented. If, however, both a therapeutic effect and a further effect that would in principle be patentable necessarily occur in combination, the method falls under the exclusion.

The assessment principle as outlined above is illustrated by the following examples:

- A method for cosmetic smoothing the skin of the face may generally be patented as being cosmetic.
- A method for muscle building, e.g. by way of electro-stimulation, may be considered as performance enhancement and accordingly be patentable.
- A method for removing plaque has also the inevitable effect of preventing caries and would be excluded from patentability, even though, only the cosmetic effect may be aimed at.
- In the therapy of diabetes mellitus, it is generally desirable to maintain the patient's blood glucose within a certain physiological target range, with little an ideally no excursion outside this target range. An advanced approach to meet this goal is the so called total artificial pancreas, respectively a closed-loop control where insulin is infused in a substantially continuous manner by way of an infusion pump and the patient's blood glucose level or an indicator thereof is continuously measured. Via a control algorithm, the blood glucose measurements are processed and used for controlling the infusion. Significant research has been and still is being carried out in this field. Straight-forward (but naïve) approaches for patenting an invention in this filed would, for example, be to claim "A method for controlling continuous insulin infusion", or "A method for controlling the blood glucose level of a patient". In both cases, however, the patentability exclusion for therapeutic methods would apply.[10]

Treatment by surgery

Among the patentability exclusions under Art. 53(c) EPC, the treatment by surgery appears to be most vague. In the authors' experience, it is the one that causes most trouble regarding medical devices. As briefly outlined in the following, it has been interpreted rather differently over time and also today there is no clear-cut rule on what qualifies for a method or method step to trigger a patentability exclusion.

For a long time, the case law called for a rather broad interpretation of "treatment by surgery", excluding in principle any method involving irreversible damage to or destruction of living cells or tissue of the living body. This was true irrespective of the underlying mechanism of the intervention, being it e.g. mechanical, electrical, thermal, or chemical. In decision **G1/07** of the Enlarged Board of Appeal , this broad definition was found to be no longer justified.

According to this landmark decision, the patentability exclusion should only apply to substantial physical interventions on the body, which require professional medical expertise to be carried out and which entail a substantial health risk even when carried out with the required professional care and expertise.

[10] An often successful solution to such a problem will be presented in the second part.

Invasive techniques of a routine character, which are performed on uncritical body parts and generally carried out in a non-medical, commercial environment, such as tattooing, piercing, hair removal by optical radiation and micro-abrasion of the skin, should not be excluded from patentability. The same should apply to medical routine interventions. The basic principle, however, that the purpose of the intervention is not decisive and a method serving a non-curative purpose, such as an embryo transfer, may well fall under the patentability exclusion still applies.

While seeming as a radical shift towards a patent-friendly and more liberal approach, the reality, however, is more complex. The (seemingly) unambiguous definitions of earlier decision where found to be too broad in **G1/07**, but no new definition was given as replacement. Instead, a case-by-case assessment was found to be more appropriate, taking into account the progressing technical and medical development.

It can be found that, while the field for inventions for medical methods has certainly expanded, there are substantive legal uncertainties. Claims directed to medical methods may in some case be objected as allegedly surgical, while other claims of in this regard virtually identical nature take the hurdle without any difficulties. Typical examples are methods that involve the placement of an infusion cannula in the subcutaneous tissue (as routinely done by a diabetic person on insulin pump therapy) or of a transcutaneous probe for determining an analyte concentration, e.g. a blood glucose concentration. According to the authors' experience, such claims may or may not be objected as "surgical".

Device-focused methods

When patenting inventions in the field of medical devices, it is common and often favorable not to only claim the device as such[11], but also methods that generally concern the technical operation of the device (in the following referred to as device-focused methods). Noteworthy, such claims may be objected under Art. 53(c) EPC as well, in particular as allegedly surgical or therapeutic methods.

Such device-focused method claims are particularly relevant in inventions that do not mainly concern a new device *per se*, but its technical way of operation. For example, the mode of operating a battery-powered device may be modified in a way that its overall energy demand is reduced. In other typical cases, the capabilities of the device for detecting device errors or malfunctions, e.g. a leakage or occlusion of an infusion line, are improved. The core of such methods does in principle not concern the medical (e.g. therapeutic) functionality of the device, but is nevertheless carried out during operation of the device.

An early landmark decision in this regard was Board of Appeal decision **T245/87**, which established the practice still in force today. The claimed method included the introduction of a (non-conductive) gas bubble into the flow of (conductive) liquid drug and measuring the electric resistance at two measuring positions. From the time required by the gas bubble for passing the distance between the measurement positions (transit time), the flow rate was determined. While originally rejected as allegedly therapeutically method, the Board of Appeal held that no patentability exclusion was justified. The reason for this view was the lack of any functional link between the claimed method and the administered drug dose. Specifically, it was found that execution of the claimed method did not influence the (therapeutic) effect of the device on the body.

Further, the method was found to be purely technical in the sense that it exclusively concerned the device designer. Regarding the therapeutic function, a physician had complete liberty to plan the operating timetable and accordingly the drug delivery as therapeutic function of the dosing device.

[11] This aspect will be looked at in more detail in the following second part of the article.

Subsequent decisions, such as **T44/12** generally confirmed the approach taken in **T245/87**. **T44/12** concerned a method for detecting an occlusion in a fluid line of a medical pump system, i.e. an infusion system. The reasoning was generally similar to **T245/87** and in a number of aspects even more liberal.

Regarding the question of whether or not a method should be objected as therapeutic (or potentially diagnostic), the criterion of the functional link is accordingly crucial. As long as any functional link, i.e. an impact on the medical device function can be excluded, patentability should not be problematic. Consequently, also a method of reducing the energy consumption of a battery powered medical device, respectively a power management method for a medical is patentable, provided that such power management does not affect the medical functionality of the device. In the case of a cardiac pacemaker, decision **T789/96** held that a method of prolonging the battery life by controlling the pulse energy was patentable if none of the method steps had a therapeutic effect.

Despite the in principle long-established and settled practice in this regard, such device-focused method claims are nevertheless still objected in a number of cases.

While it is clear from the discussion above that claims being directed towards the technical operation and having – at a first glance – no link to the medical functionality, there are a number of pitfalls in this regard. This is especially the case for methods that concern the supervising and monitoring of medical devices to ensure correct operation. In the context of such methods, it appears, besides the monitoring respectively supervision, often desirable to automatically initiate some action under certain circumstances, e.g. a malfunction.

By way of example, a method that concerns monitoring the battery state of a battery-powered medical device may in case of critically low remaining battery capacity include changing the mode of operation in a way that prolongs the battery life as far as possible. In a hypothetical example, an implantable cardiac pacemaker may be automatically switched to a stimulation mode of minimum energy consumption in case of low remaining battery lifetime. While there may be room for arguments in favor of patentability on a case-by-case basis, corresponding method claims are likely to be objected to, in the worst case resulting in a complete refusal of the patent application. A method claim that is only directed towards monitoring the battery state and providing an alert as the remaining capacity falls below a threshold, should in contrast, not be critical.

In another example, an infusion pump may automatically stop infusion in case of a blocked respectively occluded infusion line. A claim directed towards such method is also likely to be objected because of the functional link to the actual infusion.

Summary

In the medical filed, patentability exclusions for methods of treatment by therapy or surgery as well as diagnostic methods (medical methods) shall guarantee that physicians are free to treat patients in the best possible way without risking patent infringements. Products that may be used in such methods, however, are patentable. What is to be understood as medical method within this meaning is not defined by law in detail and is changing over time.

Methods respectively procedures carried out by medical devices are covered by the patentability exclusion if they execute an excluded medical method when operated. Methods that are carried by a medical device but only concern its technical function without any functional link to the its medical function, in contrast, are not affected and can be patentable. In some cases, however, they may be objected nevertheless as medical method, for example if they include switching the mode of operation in case of a malfunction.

Vorstandsmitglieder

Valentin Herbez	Präsident
Dr. Axel Remde	Vizepräsident
Frank Zeugin	Finanzen
Simon Burri	Academic – Industry Liaison

Die Vorstandsmitglieder können per E-Mail über die Gruppenwebseite (Rubrik *Vorstand*) kontaktiert werden: https://www.swissengineering.ch/web/fachgruppe-medizintechnik

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