

# Jornadas sobre patentes europeas

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# G1/07

- Magnetic resonance method for imaging the pulmonary and/or cardiac vasculature and evaluating blood flow using dissolved polarized  $^{129}\text{Xe}$ .
- Method steps: "positioning a patient in an MRI apparatus having a magnetic field associated therewith; administering polarized  $^{129}\text{Xe}$  as an imaging agent to a predetermined region of the patient's body"
- In one embodiment by inhaling, in another embodiment by **injection into the heart.**
- The imaging method may precede surgery or drug therapy. During surgery, it may provide real-time feedback and during drug therapy is may allow the effects of the drugs to be determined.
- The physical intervention on the body does not aim in itself at maintaining life and health.



# G1/07 questions

- Is a claimed imaging method for a diagnostic purpose (examination phase within the meaning given in G 1/04), which comprises or encompasses a step consisting in a physical intervention practised on the human or animal body, to be excluded from patent protection as a "method for treatment of the human or animal body by surgery" pursuant to Article 52(4) EPC if such step does not per se aim at maintaining life and health?

# G1/07 answer

- Single step enough?
  - Yes! “A method claim falls under the exclusion if **it comprises or encompasses** at least one feature defining a physical activity or action that constitutes a method step for treatment of a human or animal body by **surgery or therapy**.”
- Exclusion limited to surgery for curative (therapeutic) purposes?
  - No! Basis in Art. 53 (c). Mentions methods of treatment and methods of surgery. If treatment were the same as surgery, why mentioned apart?

# G1/07

- Then, is **any physical intervention** enough for a method to be considered surgical?
- In principle: interventions on the human or animal body that, whatever their specific purpose, **give priority to maintaining the life or health of the body**, are to be excluded.
- However:
  - The goal of the exclusion was for medical and veterinary practitioners to be free to use their skills and knowledge of the best available treatment to achieve the utmost benefit for their patients uninhibited by patents.

## G1/07

- Invasive techniques, at least when performed on uncritical parts of the body, have entailed that many such techniques are nowadays generally carried out in a non-medical, commercial environment like in cosmetic salons and in beauty parlours and **it appears, hence, hardly still justified to exclude such methods from patentability.** This applies as a rule to treatments such as tattooing, piercing, hair removal by optical radiation, micro abrasion of the skin.
- Considering this technical reality, excluding from patentability also such methods as make use of in principle **safe routine techniques, even when of invasive nature,** appears to go beyond the purpose of the exclusion of treatments by surgery from patentability in the interest of public health.

# G1/07 conclusion question 1

- Method of treatment of the body by surgery: a method in which, when carried out,
- maintaining the life and health of the subject is important and which comprises or encompasses an invasive step representing a substantial physical intervention on the body and which requires professional medical expertise to be carried out and which entails a substantial health risk even when carried out with the required professional care.
- The boundaries of the concept of treatment by surgery are to be defined by the departments of first instance and the boards of appeals.....
- An injection into the heart represents such a treatment by surgery.

## G1/07 question 2

- 2. If the answer to question 1 is in the affirmative, could the exclusion from patent protection be avoided by amending the wording of the claim so as to omit the step at issue, or disclaim it, or let the claim encompass it without being limited to it?
  - A claim which comprises a step of encompassing an embodiment which is a method for treatment of the body by surgery **cannot be left to encompass that embodiment.**
  - The embodiment may be **disclaimed**, provided the disclaimer complies with G1/03 and G2/03. (and now G2/10)
  - **The surgical step may only be omitted from the claim if the omission is compatible with Art. 84 (clarity)**, in that the step is not an essential feature defining the invention.

# G1/07

- A method which is **only concerned with the operation of a device without any functional link between the claimed method and the effects produced by the device on the body** does not qualify as a method for treatment.
  - Examples: prolonging battery life of pacemaker, checking the operation of an implanted device during drug release
- A method wherein such a functional link exists is excluded
  - Examples: method of pacing a heart with pacemaker during exercise

# G1/07 last question

- 3. Is a claimed **imaging method for a diagnostic purpose** to be considered as being a **constitutive step of a "treatment of the human or animal body by surgery"** pursuant to Article 53(c) EPC if the data obtained by the method immediately allow a surgeon to decide on the course of action to be taken during a surgical intervention?
- A claimed imaging method is not to be considered as being a "treatment of the human or animal body by surgery" within the meaning of Article 53(c) EPC merely because during a surgical intervention the data obtained by the use of the method immediately allow a surgeon to decide on the course of action to be taken during a surgical intervention.
- An independent claim must recite **all the essential features** which are necessary for clearly and completely defining the invention.

## G1/07 summary

- A claimed (imaging) method in which maintaining the life and health of the subject is important and which comprises or encompasses an invasive step representing a substantial physical intervention on the body which requires professional medical expertise to be carried out and which entails a substantial health risk when carried out with the required professional care and expertise is excluded from patentability.
- A claim cannot be left to encompass an embodiment which is a method for treatment of the human or animal body by surgery
- An independent claim must recite all the essential features which are necessary for clearly and completely defining the invention

## T 663/02

- A method of imaging an artery in a region of interest in a patient using magnetic resonance imaging and a magnetic resonance contrast agent, the method containing the steps of:
  - **injecting** the magnetic resonance contrast agent **into a vein remote from the artery**;
  - monitoring the region of interest by using a series of magnetic resonance radio frequency pulses ...;
  - detecting the arrival of the contrast agent in the region of interest ...;
  - generating an imaging initiation signal after detecting the arrival of the contrast agent in the region of interest;
  - collecting magnetic resonance image data in a magnetic resonance imaging sequence ...; and
  - constructing an image of said artery, using the magnetic resonance image data, wherein the artery appears distinct from the adjacent veins and background tissue."

# T 663/02

- Diagnostic method??
  - No, not diagnosis *stricto sensu*
  - At least phase (iv) is missing
- Surgical method that is excluded?
  - Injection of contrast agent surgical step?



## T 663/02

- The fact that an intravenous injection of a magnetic resonance contrast agent **can be delegated by a physician to a qualified paramedical professional** indicates that such an injection may be considered as representing a minor routine intervention which does not imply a substantial health risk when carried out with the required care and skill. Such acts would be ruled out from the scope of the application of the exclusion clause pursuant to Article 53(c) EPC following the narrow understanding advocated by the EBA (G 1/04 and G1/07) (Reasons, 3.2.4).

# T 663/02

- A possible way of assessing health risks is to use a risk matrix permitting to combine the **levels of likelihood and health impact** of a complication of a medical act with regard to a large number of patients, so as to obtain statistical health risk scores which may be used to decide what action should be taken. Such a risk assessment supports the view that an intravenous injection of a magnetic resonance contrast agent represents a minor routine intervention involving no substantial health risks when carried out with the required care and skill (Reasons, 3.2.5).

<i>major</i>			
<i>Health impact</i>			
<i>minor</i>			
	<i>unlikely</i>		<i>likely</i>
	<b>Likelihood of complication</b>		

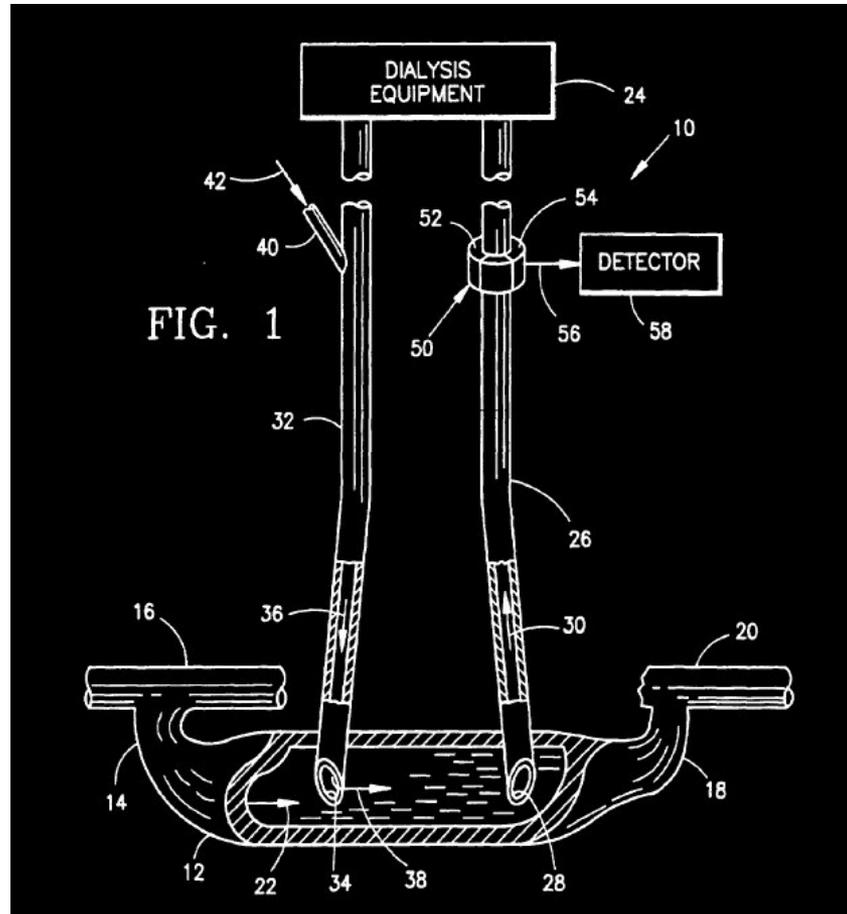
## T 663/02

- Patients with acute or chronic renal insufficiency who receive a gadolinium-based contrast agent appear to be at an increased risk for developing a Nephrogenic Systemic Fibrosis (NSF).
- **This complication, however, only depends on the injected substance.** EBA clarified in G 1/07 that there was an exclusion from patentability as a surgical method **only if the health risk was associated with the mode of administration** and not solely with the agent as such. Therefore, the complications concerning NSF and allergies are irrelevant for the issue of assessing whether the claimed method should be excluded from patentability under Article 53(c) EPC.
- Not diagnostic method, not surgical method
  - Not excluded from patentability

## T 1695/07

- 1. A process for measuring the rate of blood flow in a shunt (12) in which blood is flowing, comprising:
  - continuously removing blood from a downstream location in the shunt (12) by way of an inlet (28) to an inlet side (26) of a circulating line;
  - delivering the removed blood flowing in said circulating line by way of an outlet (34) connected to an outlet side (32) of said circulating line to an upstream location of said shunt (12), so as to cause it to travel downstream in the shunt (12) towards the inlet (28) as an admixture with the blood flow;
- changing a selected physical property of the blood in said circulating line to produce a distinguishable blood characteristic at the outlet side (32) of said circulating line;
- measuring the amount of change of said distinguishable blood characteristic; and
- determining the rate of blood flow in said shunt (12) from the amount of change of said distinguishable blood characteristic by reference to a dilution curve of said amount of change.

# T 1695/07



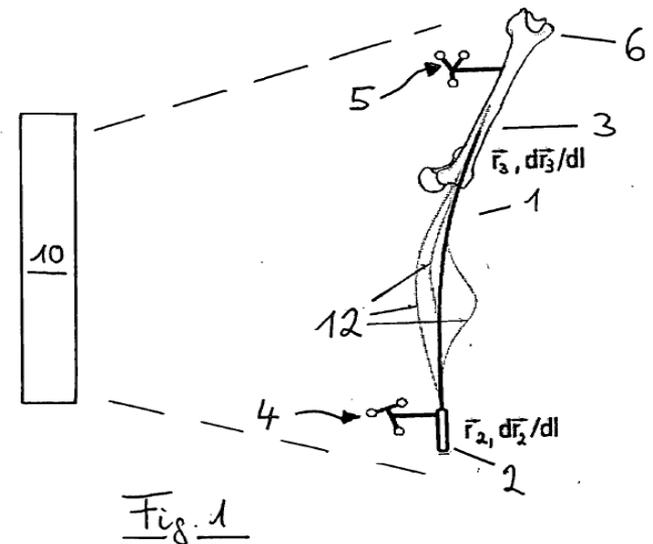
# T 1695/07

- Critical body part
- Not a minor intervention (treatment of 3 liters of blood)
- Method will be performed in clinical environment
- Requires medical expertise
- Substantial health risk
  - A health risk is considered to qualify as “substantial” whenever it goes beyond the side effects associated with treatments such as tattooing, piercing, hair removal by optical radiation, micro abrasion of skin as mentioned in G1/07.
  - A factual analysis of absolute or relative risks and their likelihood of occurrence based on objective evidence (as suggested by T 663/02) is hardly feasible and should therefore not be required.
- Conclusion: method involving at least one surgical step, not patentable

# T 836/08

- Method for determining the position of the distal end (3) of a bone guide wire (1), in which
- **with the help of a medical, optical tracking and navigation system (10)** and a reference device (4) at the proximal end (2) of the guide wire, the position and orientation of the proximal end (2) of the guide wire (1) is determined ;
- **with the help of medical, optical tracking and navigation system (10)** and a **reference device (5) attached to a bone (6)**, in whose channel, the distal end (3) of the guidewire is located, the orientation of the tubular channel in the bone (6) is determined, and in which
- ...

Reference device = IR light surgically installed

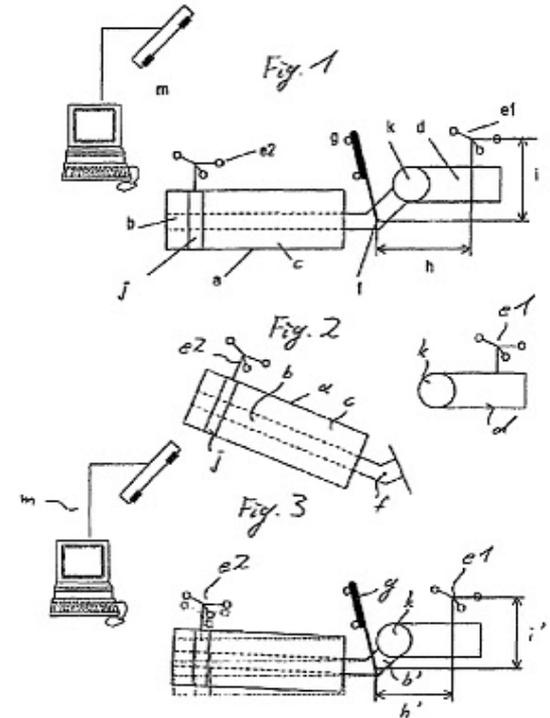


# T836/08

- No surgical step in the claimed method
- Optical tracking and navigation is not invasive
- Prior to method, surgical procedure must have been performed, but the method claim does not recite or comprise a surgical step
- Also no therapeutic effect
- Not excluded from patentability

# T 923/08

- Method for determining the change or change in length of a first object (b) which is connected in an initial state to a second object (d) via a joint (k) and which has been changed **after having been detached from the second object (d)**, wherein
- **a reference system (e1) has been attached to the second object (d) and the first object has been attached to a second reference system (e2) that is not directly fixed to the first object (b), ...**,
- **after the first object has been disconnected from the second object (d), the first object (b) has been treated and the treated first object (b) and the second object have been assembled**, the first object (b) is oriented with respect to the first reference system (e1) attached to the second object (d), using the position determined by the second reference system (e2), and
- a change of the first object (b) is determined by gathering...



## T 923/08

- As can be seen from the description, the claimed method is in particular designed to **determine the change in length of a femur when, for instance, a damaged femur head is cut off during a hip replacement surgery and is replaced by an implant.** This allows to determine the length of the operated femur as compared to its original length so that the reassembled hip joint differs as little as possible from a healthy joint [...]. **As a consequence, the recovery of the health of a human or animal body is relevant when the claimed method is carried out.**
- **An indispensable requirement for carrying out the claimed method consists in that in the initial state, i.e. before the hip replacement surgery has begun, or at its beginning, a first reference system is, preferably directly, attached to a pelvic bone, for instance by screwing it into the bone [...].** As admitted by the appellant, the desired determination of the change in length of the femur cannot be obtained without a reference system that is firmly attached to the pelvic bone.

## T 923/08

- Attaching the reference system to the pelvic bone is an invasive step representing a substantial physical intervention on the body which requires professional medical expertise to be carried out and which entails a substantial health risk even when carried out with the required professional care and expertise.
- However, the appellant is of the opinion that the attachment of the reference system to the pelvic bone is carried out before the claimed method has begun and that, consequently, the claimed method as such does not comprise an invasive step.
- The description clearly expresses that the claimed method is designed to determine the change or change in length of a femur. It does not describe any other application. Moreover, it clearly follows from it that the attachment of the first reference system to the pelvic bone is **indispensable** for the claimed method and represents an essential feature of this method because it is required for solving the problem underlying the claimed method.

## T 923/08

- Therefore, the attachment of the first reference system to the second object (pelvic bone) is an indispensable step of the method according to the invention, which is encompassed by the method claimed in claim 1 of the main request, even if it is not mentioned in the claim. (The ED has referred to this step as being “implicit” in the claim.)
- If such a step is not encompassed by the claim the requirements of A 84 (EPC 1973) are not complied with. As a matter of fact, A 84 (EPC 1973) together with R 29 (EPC 1973) requires a claim to give all the essential features that are necessary for defining the invention.
- Excluded from patentability Art. 53(c) EPC

## T 923/08 v. T836/08

- In decision T 836/08 cited by the appellant claim 1 was directed to a method for determining the distal end of a bone guidance wire by means of a medical-technical optical tracking and navigation system. This was done – in a way similar to the present situation – by means of reference apparatus situated both on the proximal end of the wire and on the bone. However, in this decision the Board has assessed the method steps that are mandatorily required in a different way and has, therefore, come to the conclusion that claims 1 to 3 only define the way in which a technical device operates and that, as a consequence, the method was optical rather than surgical.
- This shows that finally there is some margin of assessment in any individual decision and that there is no entitlement to identical decisions. Such margins of assessment are only infringed if the principles of logic or essential basic facts have been disregarded or if some other logic has been violated.

Gracias

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