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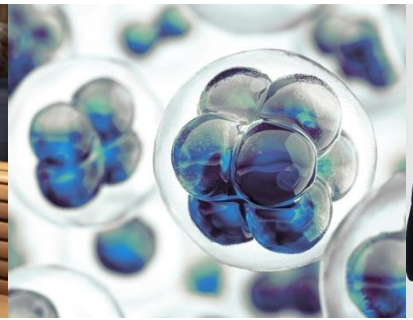
Patenting Medical Technology

Computer-implemented inventions (CII) and artificial intelligence (AI) in healthcare at the EPO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Patent examiner | Healthcare Informatics

6 October 2022

Agenda

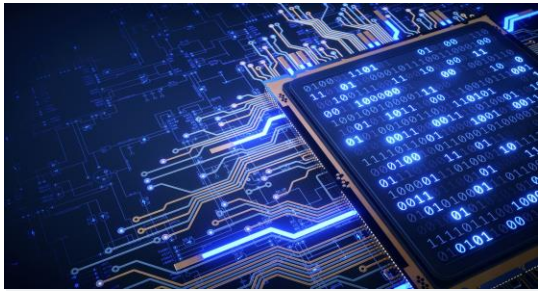
- Computer-implemented inventions (CII)
- How to obtain a patent for CII at the EPO exemplified by healthcare claims
  - 1st hurdle: Ensuring claims are not excluded from patentability
  - 2nd hurdle: Ensuring that there is an inventive step vis-à-vis the prior art
  - Intermediate step: Ensuring CII features are considered for inventive step
- Pitfalls and recommendations for applicants

What is a computer-implemented invention (CII)?

An invention…

- the implementation of which involves the use of a **computer, computer network** or other **programmable apparatus**,
- wherein one or more features of the invention are realised wholly or partly by means of a **computer program**.

→ **All software-based AI/ML inventions fall into this category**

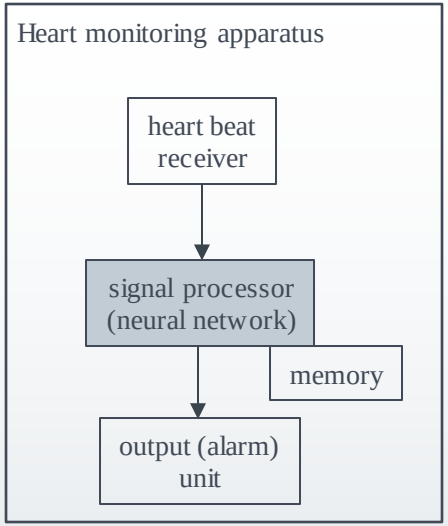


A typical example for a CII in healthcare using AI:

Use of a neural network in a heart monitoring apparatus for identifying irregular heartbeats

Typical claim set:

1. A **method** for identifying irregular heartbeats carried out by a computer comprising steps A, B, ... *
2. A data processing **apparatus/device/system** comprising means for carrying out [the steps of] the method of claim 1.
3. A **computer program [product]** comprising instructions which, when the program is executed by a computer, cause the computer to carry out [the steps of] the method of claim 1.
4. A **computer-readable [storage] medium** comprising instructions which, when executed by a computer, cause the computer to carry out [the steps of] the method of claim 1.



GL G-II, 3.3.1; GL, F-IV, 3.9

* Depending on the specific claim wording, such a method may not be allowed under Art. 53(c) EPC; GL G-II, 4.2.1.3

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What is patentable subject-matter under the EPC?

Excluded from patentability:

Inventions which are
not in a technical field

GL G-II
Art. 52(1) EPC

Not inventions:

Art. 52(2) EPC

a) discoveries, scientific theories, **mathematical methods;**
b) aesthetic creations;
c) schemes, rules and **methods for performing mental acts**, playing games or **doing business**, and **programs for computers**;
d) **presentations of information**.

→ Features relating to these items are **non-technical** (in isolation)

The first hurdle: a negative example

A method for analysing a patient record, comprising:

- selecting blood glucose data contained in the patient record, and
- analysing the selected blood glucose data via steps A-D [*relating to a non-obvious trained neural network*]

→ **The claim does not comprise a single technical feature**, but only defines mental acts and mathematical steps (non-technical features when taken in isolation).

→ **The claim is excluced from patentabillity** (not an invention within the meaning of Art. 52(1) EPC).

The first hurdle: a positive example

A **computer-implemented** method for analysing a patient record, comprising:

- selecting blood glucose data contained in the patient record, and
- analysing the selected blood glucose data via steps A-D [*relating to a non-obvious trained neural network*],

→ Any involvement of a physical step or technical entity (e.g. a computer) is sufficient to overcome the exclusion from patentability.

→ **The claim is not excluced from patentabillity**

The first hurdle: exclusion from patentability

- For the first hurdle, claims are assessed independently from any prior art.
- Claims can contain technical and non-technical features (mixed-type inventions).
- If **at least one feature** of a claim is technical, the claim is not excluded from patentability.

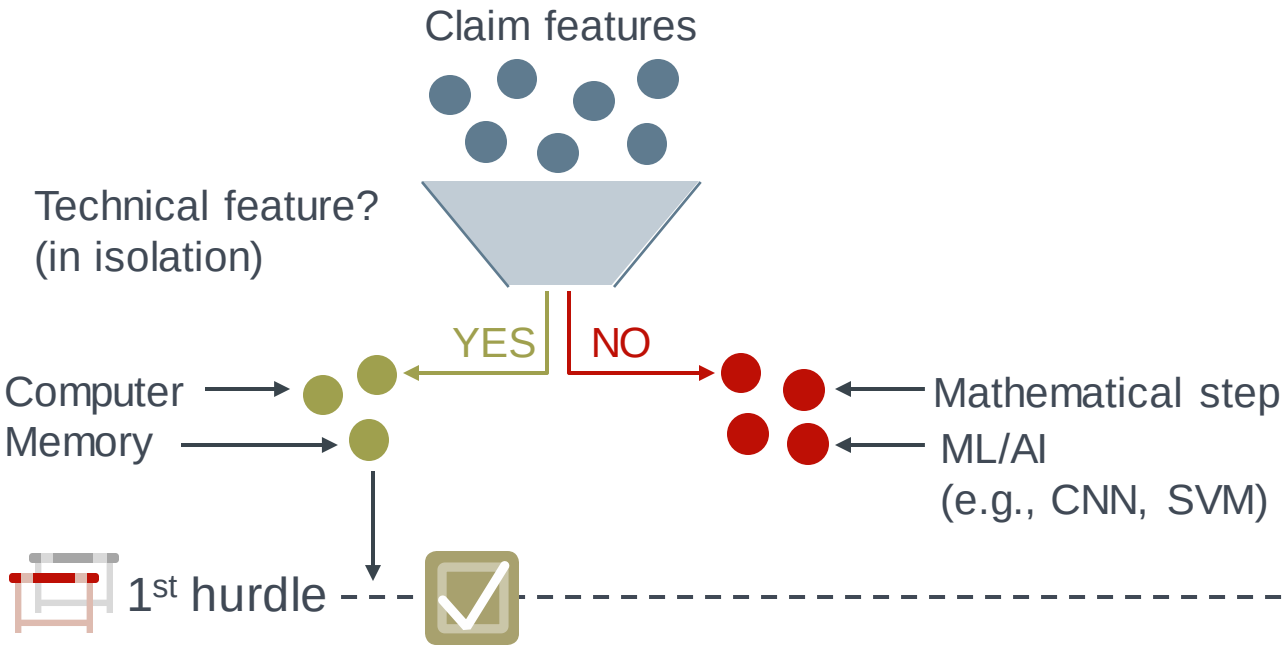
GL G-II
Art. 52(3) EPC


Method using an AI algorithm for workflow planning …


Computer-implemented AI algorithm/method for …


Device comprising a processor configured to run an AI algorithm/method for …

Visualisation of the first hurdle:



Assessing the invention's **eligibility** under Art. 52 EPC

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The second hurdle: assessment of inventive step (and novelty)

- As with all applications, claims to computer-implemented inventions also have to fulfil the requirements of **novelty and inventive step vis-à-vis the prior art**

Art. 52(1) EPC

- If all features – technical and non-technical – are known from the prior art, a claim lacks novelty

Art. 54 EPC

- **Intermediate step**: When assessing inventive step, only those features which contribute to the technical character of the invention are taken into account.

  → filter for features contributing to a technical solution of a technical problem in view of the closest prior art

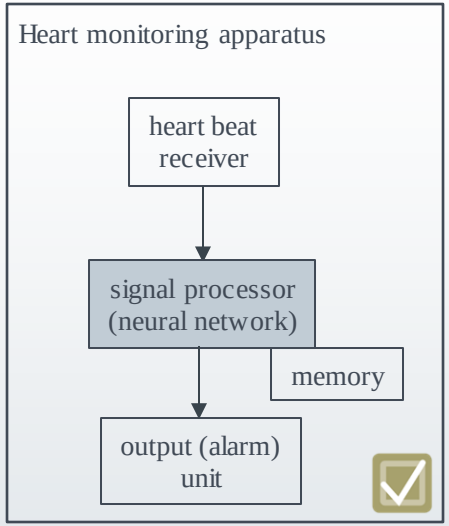
Art. 56 EPC
GL G-II, 2; G-VII, 5.4
G 1/19, r. 39; T 641/00

The second hurdle: rendering a claim inventive

For instance, even if the only distinguishing feature vs. the prior art lies in a **mathematical step** or a **ML/AI algorithm**,

…this step or algorithm **may render your claim inventive**…

as long as it **contributes to the technical character of the invention** (by producing a technical effect).



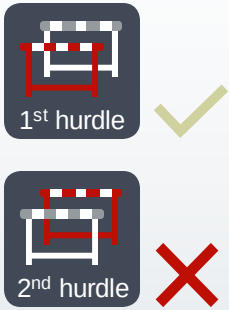
☑ CI mathematical (e.g., AI/ML) step for determining a control variable of a technical device

☒ CI mathematical (e.g., AI/ML) step for determining a billing amount for a patient

The second hurdle: a negative example

A computer-implemented method for analysing a patient record, comprising:

- selecting blood glucose data contained in the patient record, and
- analysing the selected blood glucose data via steps A-D [*relating to a non-obvious trained neural network*],



→ Analysing a patient record **without further technical implications** does not contribute to a technical effect.

→ The (in isolation) non-technical features are **not considered** when assessing inventive step.

→ The claim is **not inventive** as computer-implemented methods are obvious (even known) from the prior art.

The second hurdle: still a negative example

A computer-implemented method for analysing a patient record, comprising:

- selecting blood glucose data contained in the patient record, a
- analysing the selected blood glucose data via steps A-D [*relating to a non-obvious trained neural network*], and
- processing results of the analysis to diagnose diabetes.

→ Diagnosing diabetes based on blood glucose data of a patient is a **technical purpose.**

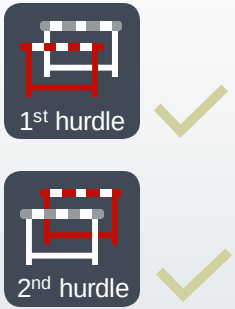
→ However, the present claim does not credibly achieve this goal. There is no **sufficient (causal) link** between the mathematical steps and the technical purpose.

GL G-II, 3.3

The second hurdle: a positive example

A computer-implemented method for diagnosing diabetes, comprising:

- selecting blood glucose data contained in the patient record,
- analysing the selected blood glucose data via steps A-D [*relating to a non-obvious trained neural network*], and
- processing [*well-defined*] results of the analysis via further steps E-G to [*credibly*] diagnose diabetes.

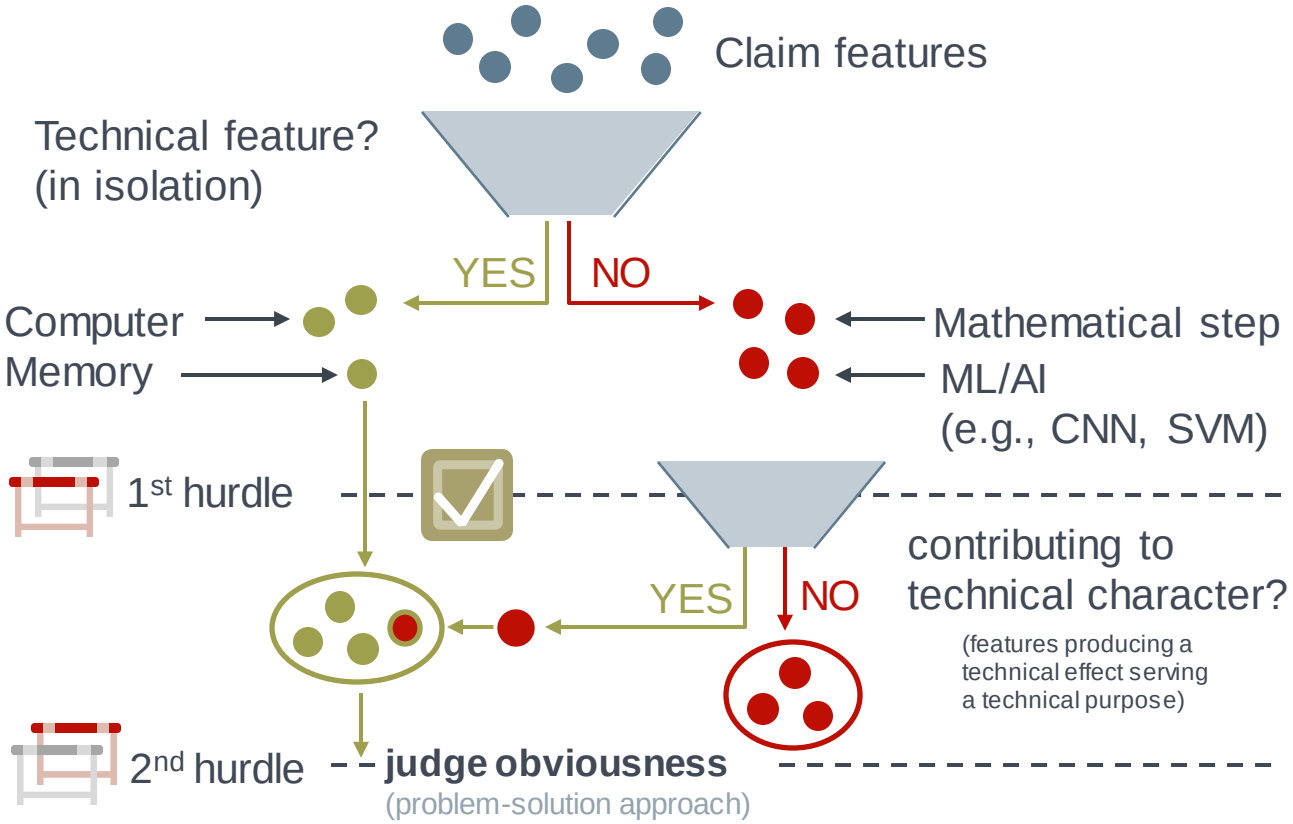


→ The non-technical step features of the method now **contribute to produce a technical effect** since they credibly serve the technical purpose of diagnosing diabetes.

→ Therefore, the (in isolation) non-technical features are to be **considered when assessing inventive step**.

GL G-VII 5.4
GL G-II 4.2.1.3

Visualisation of the first and second hurdle:



1. Assessing the invention's **eligibility** under Art. 52 EPC
2. Test eligibility of the features to contribute to inventive step
3. Assessment of inventive step vis-à-vis the prior art (**patentability**)

A contribution to technical character…

…of mathematical (AI/ML) features or other non-technical features can be achieved in **two dimensions:**

1. Application to a field of technology

- The claim specifies (explicitly or implicitly) how the output of the mathematical method is used. The use is technical.

2. Adaptation to specific technical implementation

- Specific adaption to exploit the hardware.
- Design based on technical considerations relating to the internal functioning of the computer.

GL G-II, 3.3
T 2330/13, T 1925/11

First dimension: application to a field of technology

Claim drafting: What is required?

- The technical purpose should be specific, i.e. not generic and *pro forma* such as "*controlling a [any] technical system*".

GL G-II, 3.3

- The mathematical (ML/AI) steps must be causally linked to a technical effect: Additional specifications as to how input and output relate to the technical purpose are normally necessary to establish the contribution of the mathematical steps to technical character.

First dimension: examples of application to a field of technology (e.g. of AI/ML techniques)

- ☑ Controlling a specific technical system or process, e.g. an X-ray apparatus
- ☑ Compression of audio, image, video or sensor data
- ☑ Encrypting/decrypting or signing electronic communications
- ☑ Providing a medical diagnosis by an automated system processing physiological measurements
- ☑ Device for guiding a surgeon during a medical procedure
- ☑ Modelling of the progression of an HIV infection in a specific patient

GL G-II, 3.3

First dimension: examples of application to a field of technology (e.g. of AI/ML techniques)

- ☑ Modelling of patient specific body parts used to derive a surgical procedure
- ☑ Deriving therapeutic treatment plan for specific patients from data analysis
- ☑ Device for checking adherence to medication intake by automatic means
- ☒ Hospital resources management
- ☒ Patient appointment or invoice management
- ☒ Simulating physical/biological systems to gain scientific knowledge

GL G-II, 3.3
G 1/19, r. 98

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Pitfall: insufficient detail in the claim

The mere fact that mathematical or other non-technical method steps **may** serve a technical purpose is not sufficient:

- The claim has to be **functionally and causally limited** to the technical purpose, either explicitly or implicitly, i.e. there must be a **sufficient link** between the mathematical or other non-technical method steps and the technical purpose, so that they are **causally/credibly linked**.
- The claim must be **technical over its whole scope**.
- Thus, if **essential steps are missing or are defined in vague or overly generalised terms**, an (AI/ML) algorithm may not be taken into account for inventive step.

GL G-II, 3.3
G 1/19, r. 82 – 84, 111 - 117

Pitfall: no fallback positions in the application

Insufficient details in the claims may be overcome by amendment to specify more detailed steps (i.e. fallback positions):

- However, any amendment must be **directly and unambiguously derivable** from the application as **originally filed.**
- Therefore, any clarification of terms or detail required to define the invention must be included when drafting the application.
- Failure to do so may result in unresolvable objections.

Art. 123(2) EPC

Pitfall: insufficient disclosure (of ML/AI algorithms and their training)

Art. 83 EPC

- The patent application shall disclose the invention **sufficiently clear and complete** for the invention to be carried out by the person skilled in the art.

- The description must disclose **sufficient details of the main aspects of the invention** to allow the person skilled in the art, using common general knowledge, to perform the invention over the whole area claimed without undue burden and without needing inventive skill.

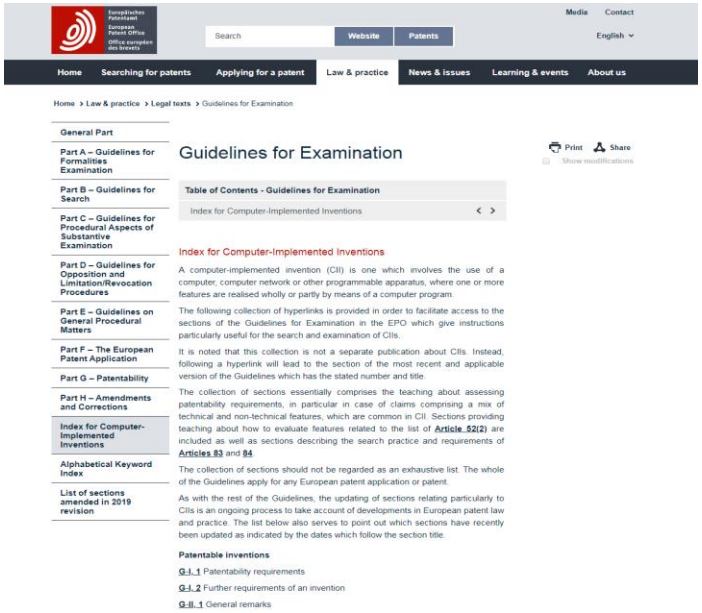
- ML/AL algorithms and their training must be sufficiently disclosed.

Conclusion: how to obtain a patent for CII at the EPO

- The claims must contain **at least one technical feature**, for example a computer.
- The claims must be **new and inventive** over the prior art.
- Non-technical claim features as such are considered for inventive step, **only if** they **produce a technical effect serving a technical purpose** in the context of the invention.
- The claim features must be **sufficiently detailed** and linked to the technical purpose.
- The description must disclose **sufficient details of the invention**.

The EPO's CII practice: worldwide benchmark

https://www.epo.org/law-practice/legal-texts/html/guidelines/e/j.htm



Introductory information for CII patents

EPO - Digitale Technologien and its sub-links, in particular:

- EPO - Hardware and software

- EPO – Artificial intelligence
  (in particular section “AI and patentability”)

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