



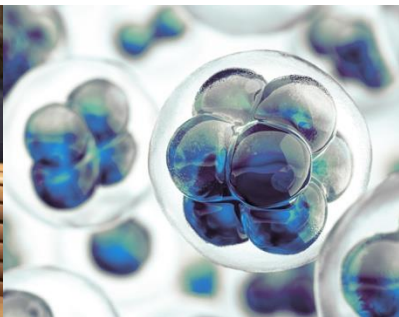
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# Patenting Medical Technology

Computer-implemented inventions (CII) and artificial intelligence (AI)  
in healthcare at the EPO



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# Agenda

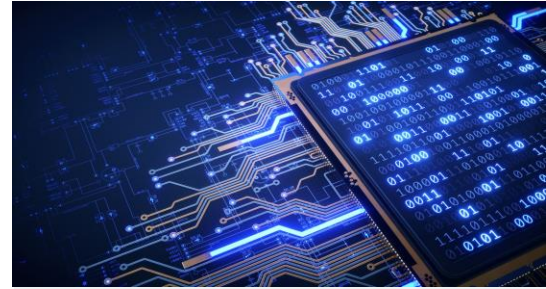
- Computer-implemented inventions (CII)
- How to obtain a patent for CII at the EPO exemplified by healthcare claims
  - 1<sup>st</sup> hurdle: Ensuring claims are not excluded from patentability
  - 2<sup>nd</sup> hurdle: Ensuring that there is an inventive step vis-à-vis the prior art
  - Intermediate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

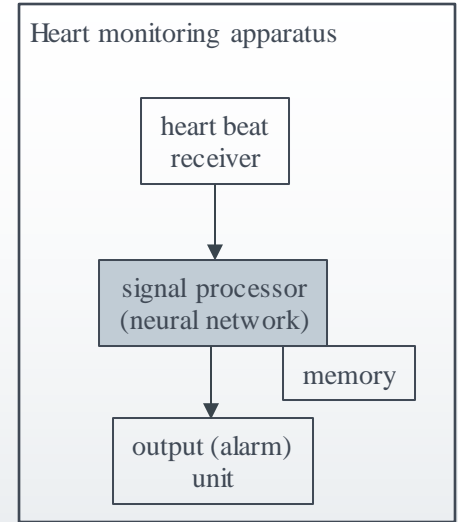


# A typical example for a CII in healthcare using AI:

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:**

- 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**.

Art. 52(2) EPC

→ 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 excluded from patentability** (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 excluded from patentability**





# 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.

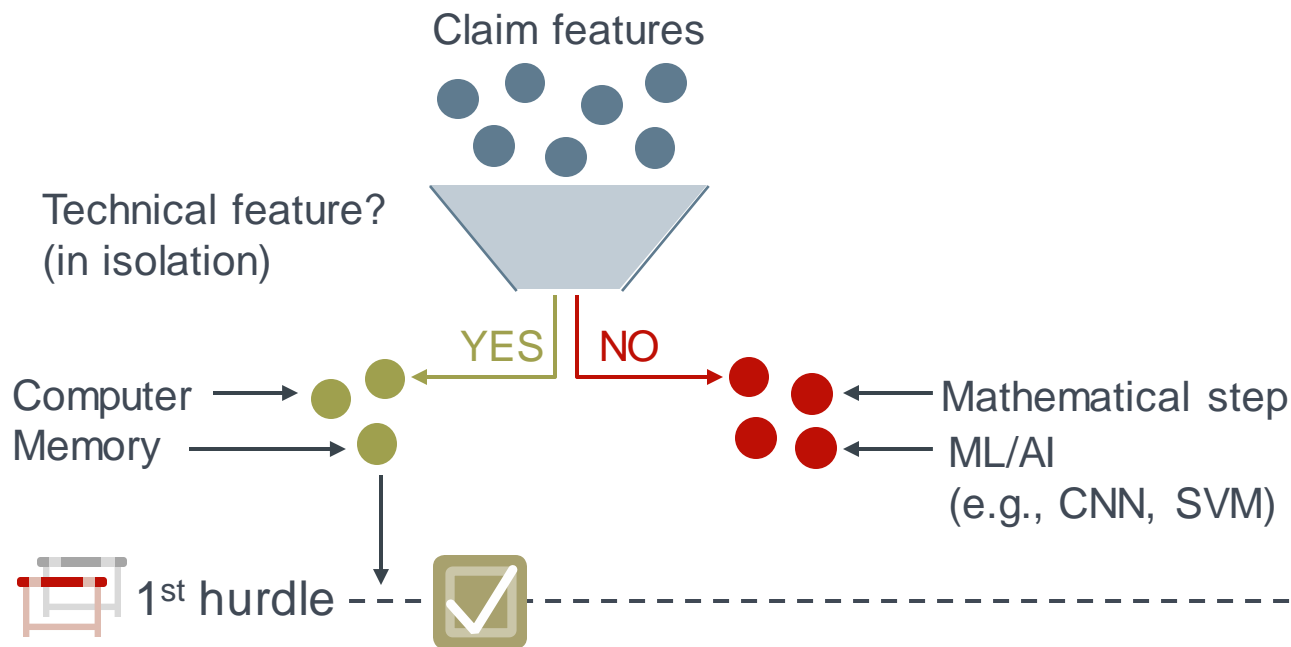
Method using an **AI algorithm** for workflow planning ...

Computer-implemented **AI algorithm/method** for ...

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

GL G-II  
Art. 52(3) EPC

# 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**
- If all features – **technical** and **non-technical** – are known from the prior art, a claim lacks novelty
- **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. 52(1) EPC

Art. 54 EPC

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

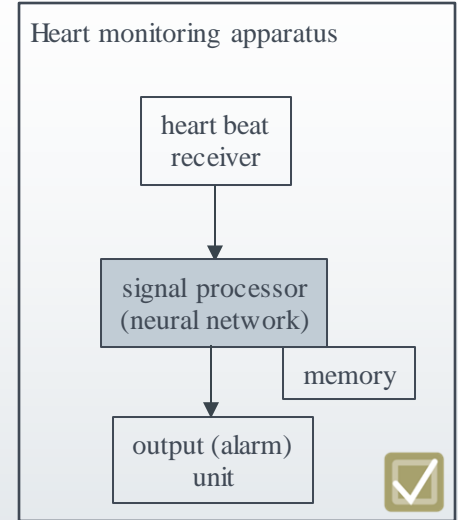
For instance, even if the only distinguishing feature vs. the prior art lies in a **mathematical step** or a **ML/AI algorithm**,

...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

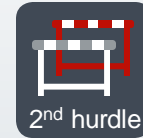
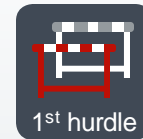
## The second hurdle: a positive example

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.

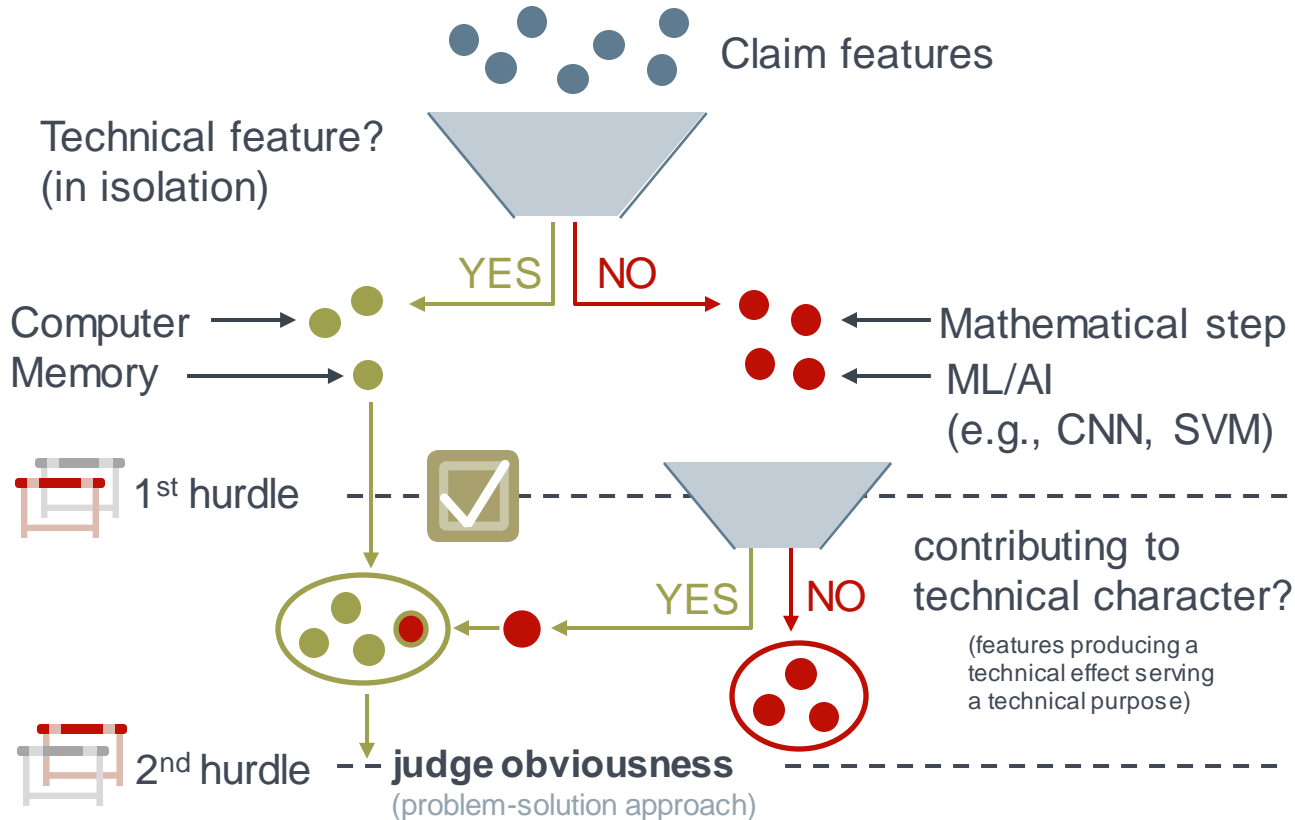
→ Therefore, the (in isolation) non-technical features are to be **considered when assessing inventive step**.



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*".
- 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.

GL G-II, 3.3

## 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

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Deriving therapeutic treatment plan for specific patients from data analysis

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Device for checking adherence to medication intake by automatic means

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Hospital resources management

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Patient appointment or invoice management

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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>

The screenshot displays the EPO website interface. At the top, there is a navigation bar with the EPO logo, a search box, and links for 'Website' and 'Patents'. Below this is a secondary navigation bar with links for 'Home', 'Searching for patents', 'Applying for a patent', 'Law & practice', 'News & issues', 'Learning & events', and 'About us'. The main content area is titled 'Guidelines for Examination' and includes a 'Table of Contents - Guidelines for Examination' with a sub-entry for 'Index for Computer-Implemented Inventions'. The page also features a 'Print' and 'Share' button, and a 'Show modifications' link. The left sidebar contains a 'General Part' menu with links to various parts of the guidelines, including 'Part A - Guidelines for Formalities Examination', 'Part B - Guidelines for Search', 'Part C - Guidelines for Procedural Aspects of Substantive Examination', 'Part D - Guidelines for Opposition and Limitation/Revocation Procedures', 'Part E - Guidelines on General Procedural Matters', 'Part F - The European Patent Application', 'Part G - Patentability', and 'Part H - Amendments and Corrections'. Below the menu is an 'Index for Computer-Implemented Inventions' section with an 'Alphabetical Keyword Index' and a 'List of sections amended in 2019 revision'.

Home > Law & practice > Legal texts > Guidelines for Examination

## Guidelines for Examination

Table of Contents - Guidelines for Examination

Index for Computer-Implemented Inventions

### Index for Computer-Implemented Inventions

A computer-implemented invention (CII) is one which involves the use of a computer, computer network or other programmable apparatus, where one or more features are realised wholly or partly by means of a computer program.

The following collection of hyperlinks is provided in order to facilitate access to the sections of the Guidelines for Examination in the EPO which give instructions particularly useful for the search and examination of CII.

It is noted that this collection is not a separate publication about CII. Instead, following a hyperlink will lead to the section of the most recent and applicable version of the Guidelines which has the stated number and title.

The collection of sections essentially comprises the teaching about assessing patentability requirements, in particular in case of claims comprising a mix of technical and non-technical features, which are common in CII. Sections providing teaching about how to evaluate features related to the list of **Article 82(2)** are included as well as sections describing the search practice and requirements of **Articles 83 and 84**.

The collection of sections should not be regarded as an exhaustive list. The whole of the Guidelines apply for any European patent application or patent.

As with the rest of the Guidelines, the updating of sections relating particularly to CII is an ongoing process to take account of developments in European patent law and practice. The list below also serves to point out which sections have recently been updated as indicated by the dates which follow the section title.

#### Patentable inventions

**Q.1.1** Patentability requirements

**Q.1.2** Further requirements of an invention

**Q.8.1** General remarks

# Introductory information for CII patents

[EPO - Digitale Technologien](#) and its sub-links, in particular:

- [EPO - Hardware and software](#)

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What do patents for CII look like?	<b>Claim formulations for CII</b>	<b>Legal basis for CII</b>	<b>Case Law</b>
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- [EPO – Artificial intelligence](#)

(in particular section “AI and patentability”)

# Where to get additional information/help

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