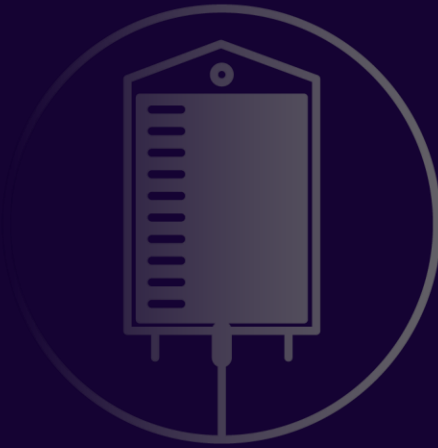


Patenting Computer-Implemented Healthcare Inventions in Artificial Intelligence and Machine Learning

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Overview

- Introduction to AI and Machine Learning
- Statistics: patenting medical devices and AI related inventions
- Review of patentability requirements in Europe
- Examples
- Update on AI inventorship
- Conclusions



What are AI and ML?

AI (Artificial Intelligence)

machines that can become better at a task typically performed by humans with limited or no human intervention

ML (Machine Learning)

an AI process that uses algorithms and statistical models to allow computers to make decisions without having to explicitly program it to perform the task

Definitions from https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1055.pdf



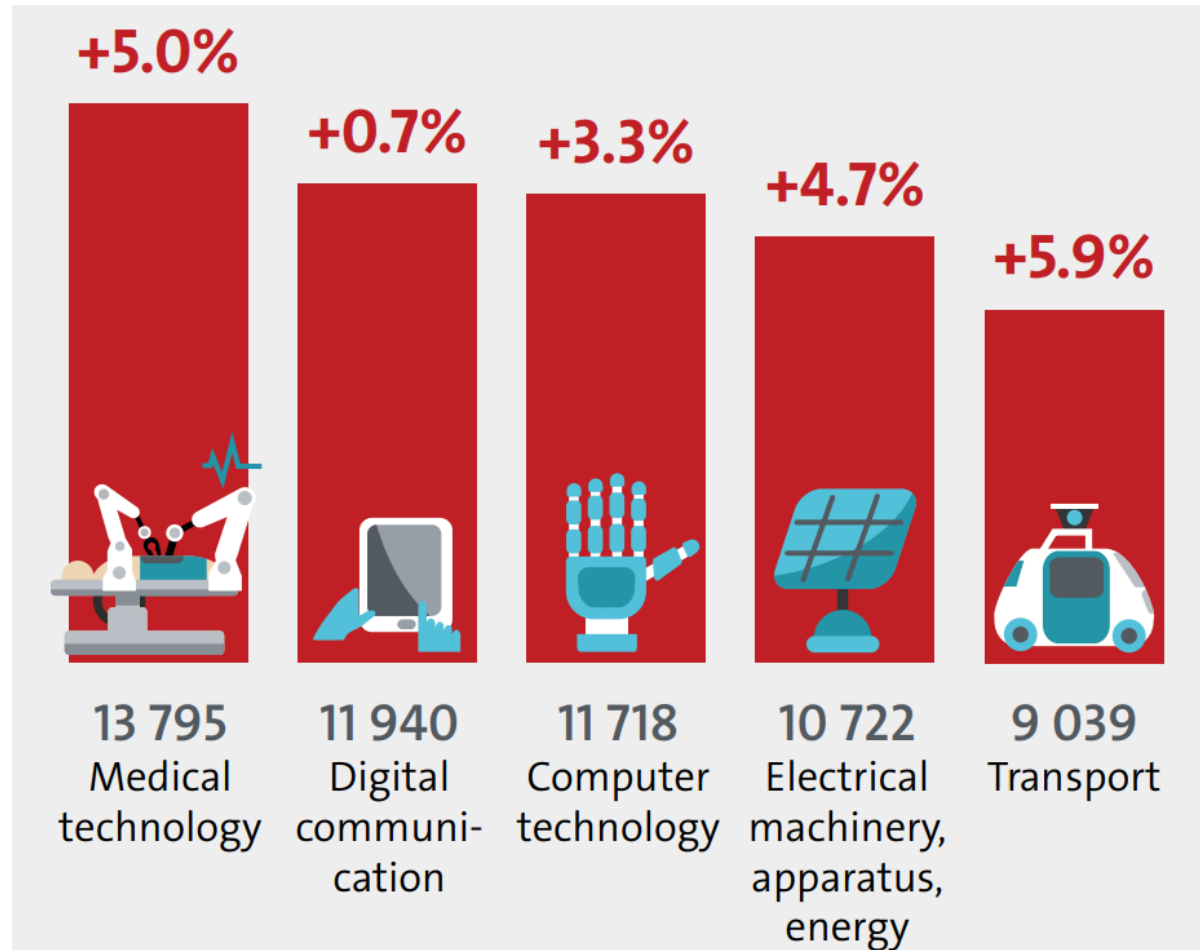
AI/ML in medical applications

AI/ML is being used in:

- Breast Cancer Screening (Qlarity Imaging)
- Stroke Detection (VIZ.AI)
- Patient monitoring (Philips Healthcare)
- AI predicted Acute Kidney Injury, AKI (DeepMind)
- Drug development (Exscientia)
- And more!



Key growth areas: Medical Technology



Source: EPO annual report 2018



Key growth areas: AI



Source: WIPO Technology Trends 2019



Legal Requirements for patentability in Europe

Identify contribution which is:

- Novel
- Inventive
- Technical



Legal Requirements for patentability in Europe

Navigate several patentability exclusions

- Mathematical method, computer program, method for treatment, surgery or diagnosis performed on the human or animal body
- Can be possible to work around mathematical method or computer program exclusions
- One feature which relates to a surgical or therapeutic step can “pollute” the entire claim
- Careful patent drafting is important!

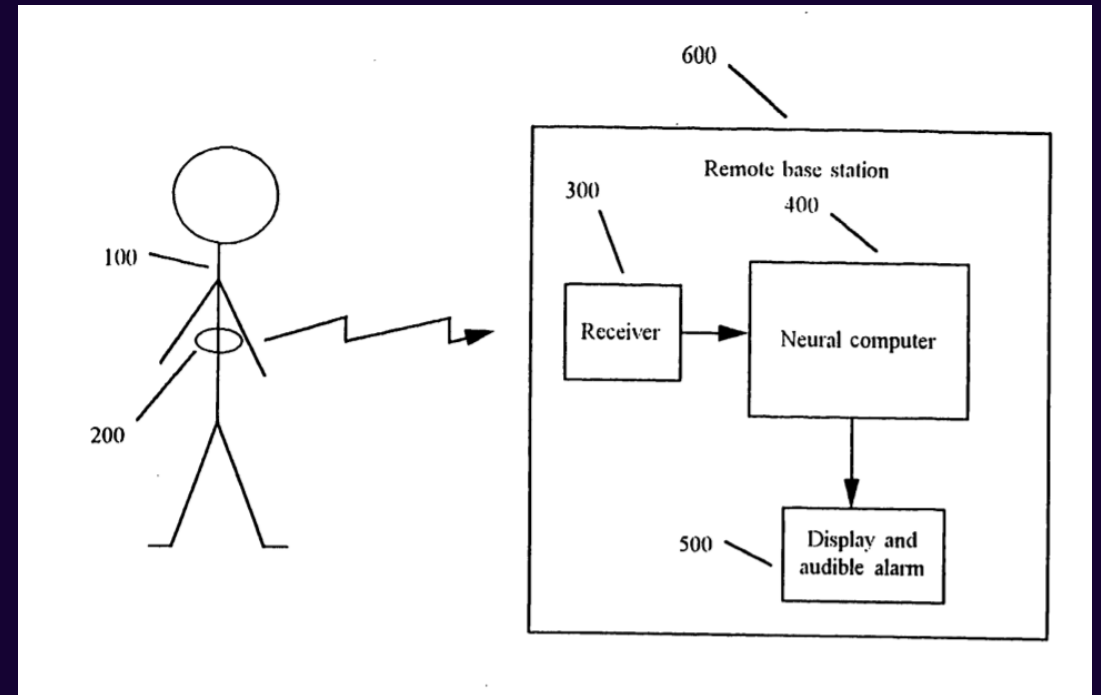


Example 1: AI analysis of medical data

Based on T598/07



*Heart monitoring apparatus comprising:
input means for receiving an ECG
signal from a patient; and
neural network... to identify
distinctive irregular heartbeats spurious
with regard to monitoring heart
conditions... and determine if ECG pulses
not including the distinctive irregular
heartbeats are within or outside of a
regular heartbeat n dimensional volume.*



Example 1: AI analysis of medical data

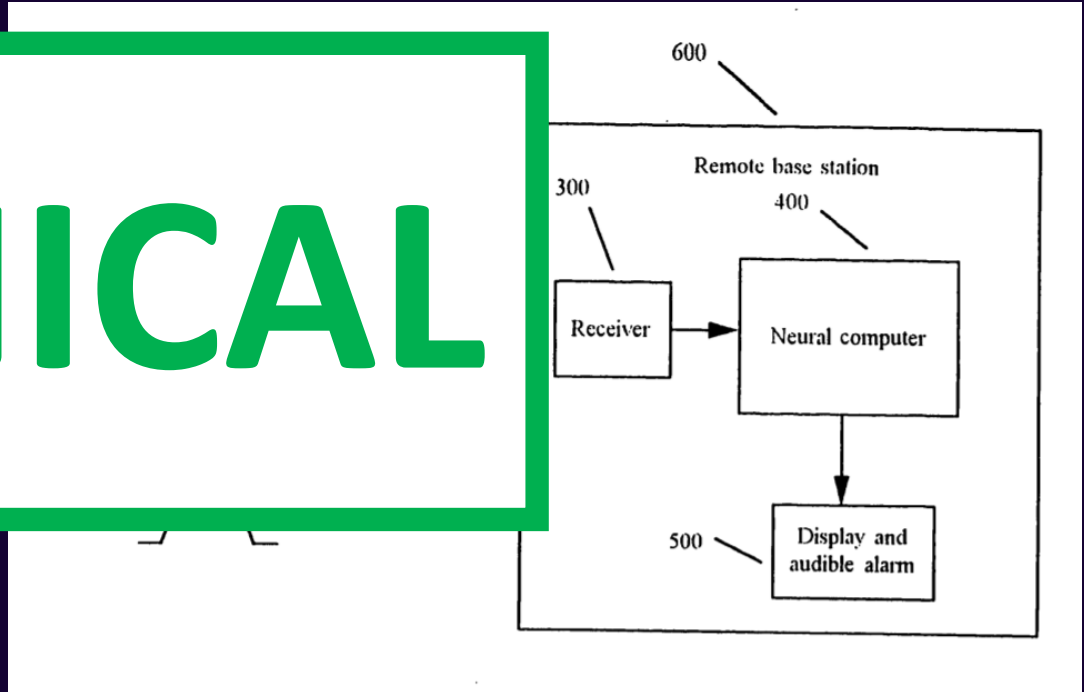
Based on T598/07



Heart monitoring apparatus comprising:

input means for receiving an ECG signal from a patient; a neural network for analyzing the signal to determine if the signal is distinctive irregular with regard to morphology and duration of the heartbeats... and a display and audible alarm for alerting the patient or a caregiver when the signal is not including the distinctive irregular heartbeats are within or outside of a regular heartbeat n dimensional volume.

TECHNICAL



Example 1: AI analysis of medical data

AI based analysis of medical data can provide a technical effect, in this case to reduce false identifications of novel ECG signals, and thus be patentable.

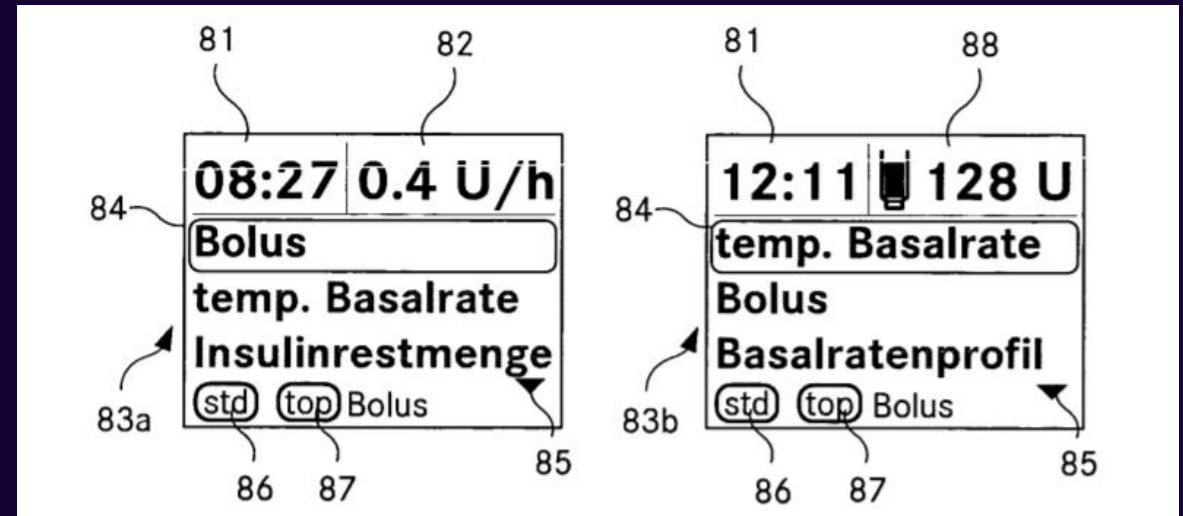


Example 2: Self-learning Medical Devices

Based on T1779/14



An insulin pump with a graphical user interface for displaying menu items, wherein the choice and order of displayed menu items depends on a user-specific preference profile and a current time, wherein the profile is updated based on a statistical analysis of user inputs



Example 2: Self-learning Medical Devices

Based on T1779/14

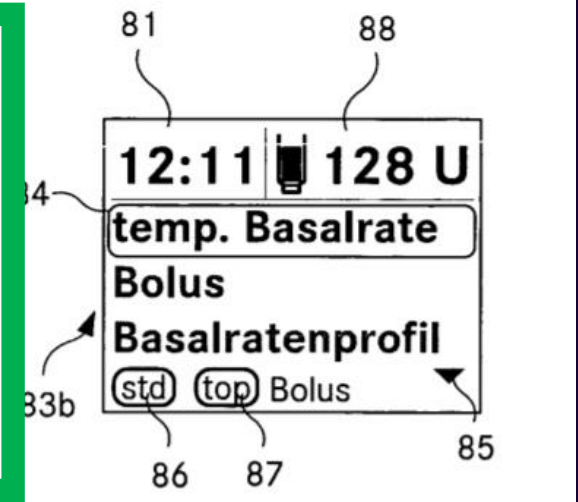


An insulin pump with a graphical user interface for displaying

wherein the displayed menu items are user-specific preferences at current time,

wherein the profile is updated based on a statistical analysis of user inputs

TECHNICAL



Example 2: Self-learning Medical Devices

Self-learning aspect used to provide a technical effect – improved interface for reduced screen size.

Self-learning aspect alone would most likely not have been sufficient for patentability. The improved interface was key.



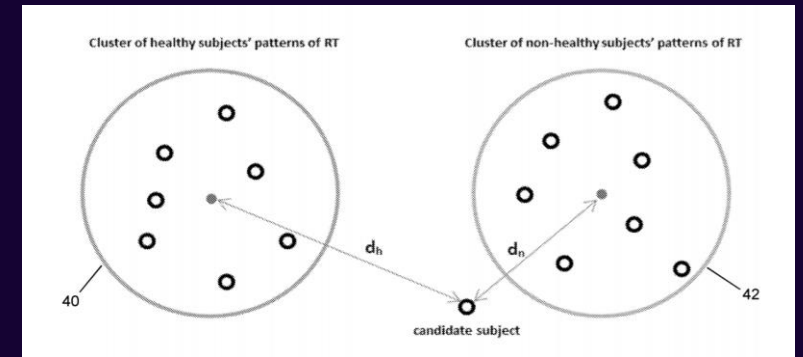
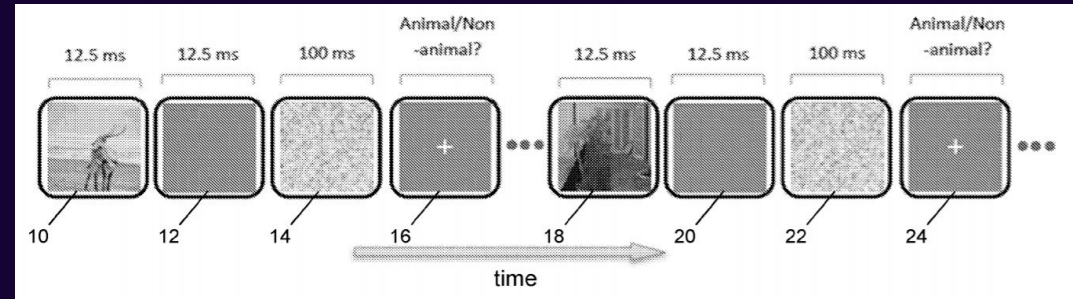
Example 3: Diagnosing Mental Health Disorder

Based on EP3065641



A system for assessing a mental health disorder in a human subject comprising:

- controller to display test images and generate response data; and*
- data processor to compare the response data with reference data to assess whether the subject has the mental health disorder,*
- wherein the control processor is to cause display of each test image for 10 ms, followed by a blank screen for 10 ms, followed by a noisy mask for 100 ms or longer.*



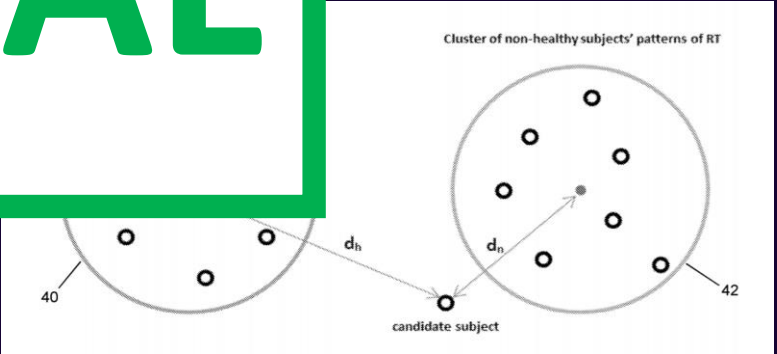
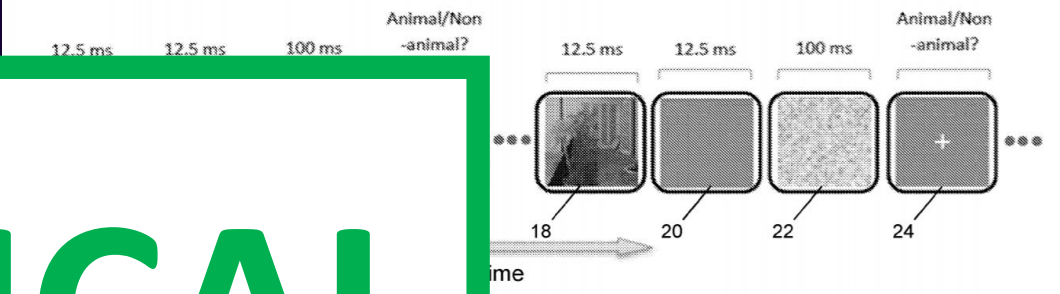
Example 3: Diagnosing Mental Health Disorder

Based on EP3065641



A system for assessing a mental health disorder in a human subject comprising a controller to generate response data, a data processor to compare the response data with reference data, wherein the controller is configured to display of each test image for 10 ms, followed by a blank screen for 10 ms, followed by a noisy mask for 100 ms or longer.

TECHNICAL



Example 3: Diagnosing Mental Health Disorder

New type of diagnostic test performed by an automated Machine Learning system considered technical and patentable.

Consistent with T1814/07:

“even steps of a diagnosis method not having a technical nature may cause a technical effect in an automated system implementing the diagnosis method”

“Medical engineering as a field is not included in the recitations of Article 52(2) EPC, nor is there any reason to consider it a "non-technical" art as a whole. The solution of a medical problem, e.g. how to determine a new diagnosis or treatment, cannot therefore be equated with e.g. the solution of a business problem.”

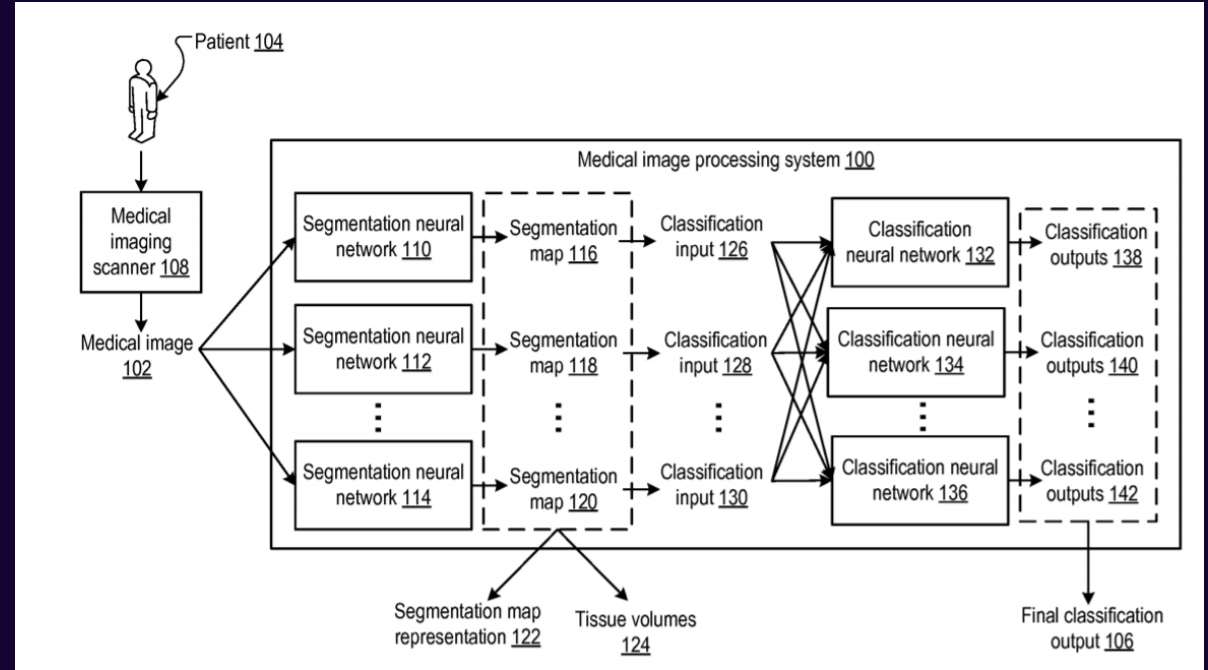


Example 4: ML for classifying images

Based on EP3596697 (still pending!)



A system to
 segment an image of eye tissue using
 segmentation neural networks;
 generate, from the segmented
 image, a classification input;
 provide the classification input as
 input to classification neural networks to
 obtain a respective classification output
 from each classification neural network;
 and generate, from the respective
 classification outputs, a final classification
 output for the image.



Example 4: ML for classifying images

Merely using neural networks over other techniques not considered inventive.

Downsampling segmented image to provide classification input appears to be sufficient to render claim 1 inventive – preparing data for classification neural network



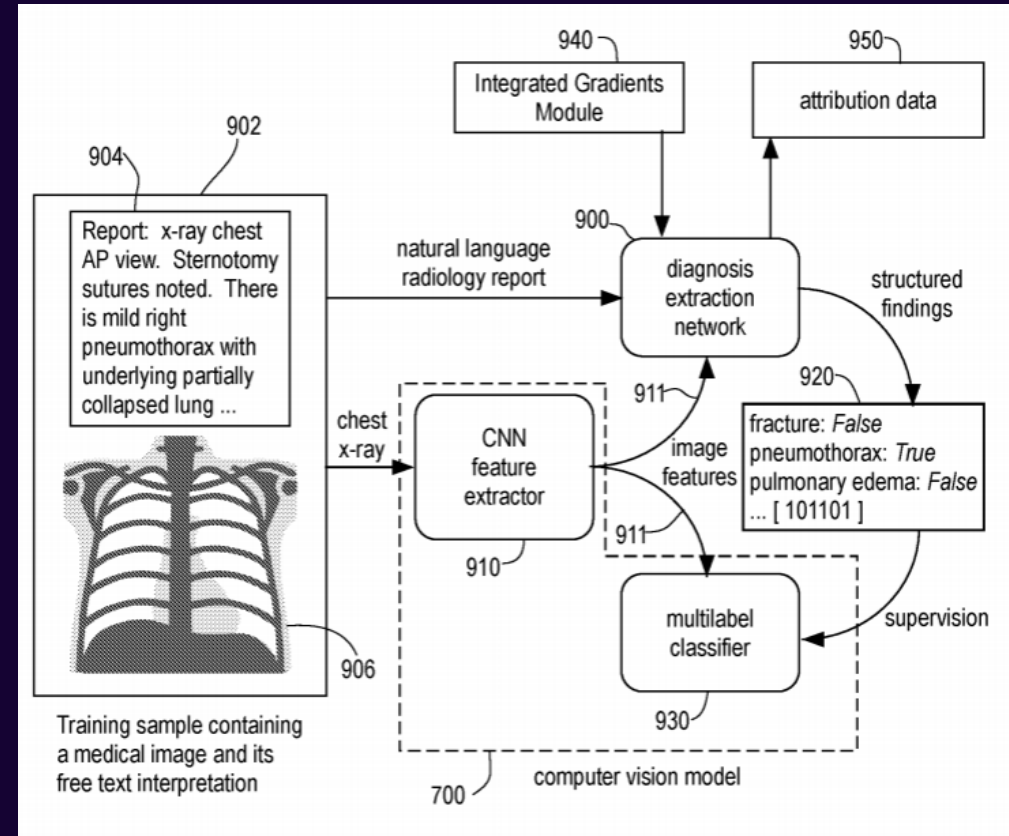
Example 5: Processing medical text and images

Based on WO2019160557 (still pending!)



A system for processing medical text and associated medical images comprising:

- a natural language processor trained on a first corpus of medical reports having structured labels;*
- a second corpus of medical reports associated with medical images, wherein the natural language processor is applied to the second corpus and generates structured labels for the associated medical images; and*
- a computer vision model trained on the medical images and the structured labels generated by the natural language processor to assign a structured label to a further input medical image.*



Example 5: Processing medical text and images

Initial indications are that this is not considered to be sufficiently technical.

Structured label considered nothing more than meta information about the image content.

No technical or physiological teaching claimed as to how the label is actually derived from medical information sources except for the fact that the machine learning related to texts and images plays a role.



AI Inventorship (EPO)

AI “Inventor”: DABUS

In Sachen der oben bezeichneten europäischen Patentanmeldung nennt (nennen) der (die) Unterzeichnete(n)¹/ In respect of the above European patent application I (we), the undersigned¹/ En ce qui concerne la demande de brevet européen susmentionnée, le(s) soussigné(s)¹

THALER, Stephen L.
1767 Waterfall Dr.
St Charles 63303
Missouri

als Erfinder²: / do hereby designate as inventor(s)²: / désigne(nt) en tant qu'inventeur(s)²:

DABUS – The invention was autonomously generated by an artificial intelligence
1767 Waterfall Dr.
St Charles 63303
Missouri



AI Inventorship (EPO)

II. Reasons for the decision

Indication of the inventor in the designation of inventor

19. The application designates a machine as the inventor and therefore does not meet the formal requirements under the EPC (Article 81, Rule 19(1) EPC).
20. Article 81 EPC prescribes that the European patent application designate the inventor and that, if the applicant is not the inventor, it contain a statement indicating the origin of the right to the European patent. In accordance with Rule 19(1) EPC, the designation shall state the family name, given names and full address of the inventor and, in cases such as the one at hand where the applicant is not the inventor, the designation shall contain a statement indicating the origin of the right to the European patent and bear the signature of the applicant or his representative.²
21. Indicating the name of a machine (DABUS) does not meet the requirements of Rule 19(1) EPC.



AI “Inventor” (UK IPO)

- Accepted that DABUS created the inventions
- BUT machine cannot be regarded as inventor
- AND no law which allows for transfer of ownership of invention from inventor to owner because inventor cannot hold property



Conclusions

- AI/ML related inventions in medical technology can be patentable
- Several different patentability exclusion provisions have to be navigated
- How the patent is drafted is important
- AI cannot (at least yet) be an inventor in the UK and Europe



Thank you

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