



**25 October 2016**

Topic group 1: Medical devices

## **Main (EPO) objections faced by applicants**

Expert seminar on medical devices, green inventions and non-technical features

OS16-2016, 25 to 27 October 2016 - Bern, Switzerland

- European Patent Attorney
- Engineer in materials science
- 18 years as French Patent Attorney in a Private Practice (Paris)
- Since 2013 Patent attorney at P&TS, based in Neuchâtel.





-> *Protecting innovations from competition*



-> Filing and litigating patents in different countries





Integrate many technologies.

Example: medical device;  
mechanical parts; computer;  
materials

It is impossible for a single  
company to be #1 in all those  
fields.

Partners required at all stages:  
R&D, proof of concept,  
manufacturing, selling

-> Possible inventions at all stages !



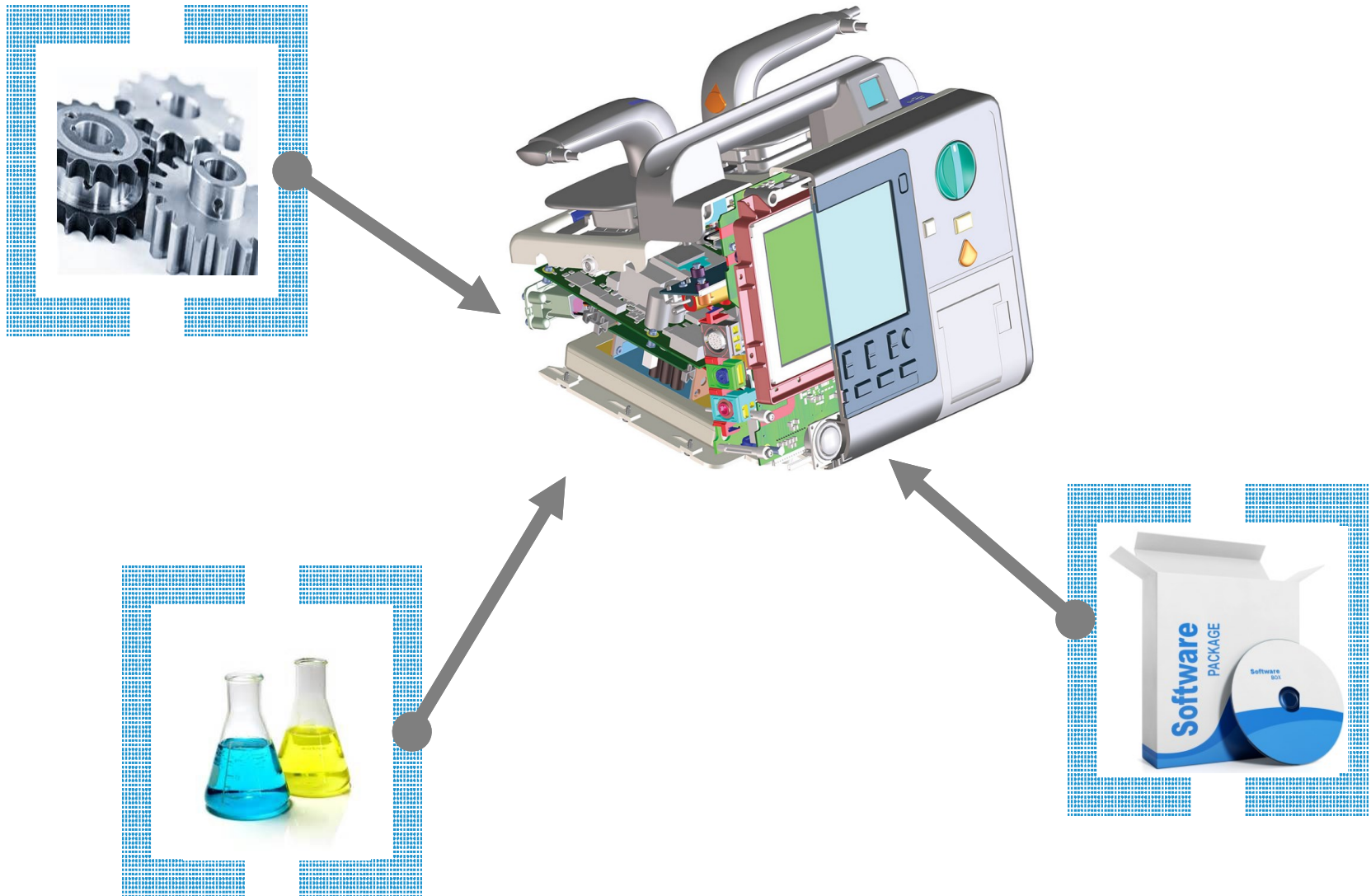
What seems important and innovative to the applicant might not be what **could** be possibly patented:

- > prior art
- > non-patentable subject matter

What seems important and innovative to the applicant might not be what **should** be patented :

- > evidence of infringement for a method is far more difficult to obtain than for the physical structure of the product
- > are possible variant also protected ?    workaround ?

# Licensing various technologies into one product





Our profession is not only about walls.

Our profession is also about bridges between companies.

Finding the right bridge:  
-> between the technical content of the invention and the legal requirements

-> between the applicant's needs and the EPO legal requirements



## Article 53 EPC

*European patents shall not be granted in respect of:*

*(c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised 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.*

## Claims



1. Use of MCAM as a biomarker for diagnosing, predicting, and/or prognosticating acute heart failure (AHF) in a subject.



## MCAM

(Melanoma cell adhesion molecule)

is a new marker

For the specific disease Acute  
Heart Failure



```

Met Gly Leu Pro Arg Leu Val Cys Ala Phe Leu Leu Ala Ala Cys Cys
1      5      10      15
Cys Cys Pro Arg Val Ala Gly Val Pro Gly Glu Ala Glu Gln Pro Ala
20      25      30
Pro Glu Leu Val Glu Val Glu Val Gly Ser Thr Ala Leu Leu Lys Cys
35      40      45
Gly Leu Ser Gln Ser Gln Gly Asn Leu Ser His Val Asp Trp Phe Ser
50      55      60
Val His Lys Glu Lys Arg Thr Leu Ile Phe Arg Val Arg Gln Gly Gln
65      70      75      80
Gly Gln Ser Glu Pro Gly Glu Tyr Glu Gln Arg Leu Ser Leu Gln Asp
85      90      95
Arg Gly Ala Thr Leu Ala Leu Thr Gln Val Thr Pro Gln Asp Glu Arg
100     105     110
Ile Phe Leu Cys Gln Gly Lys Arg Pro Arg Ser Gln Glu Tyr Arg Ile
115     120     125
Gln Leu Arg Val Tyr Lys Ala Pro Glu Glu Pro Asn Ile Gln Val Asn
130     135     140
Pro Leu Gly Ile Pro Val Asn Ser Lys Glu Pro Glu Glu Val Ala Thr
145     150     155     160
Cys Val Gly Arg Asn Gly Tyr Pro Ile Pro Gln Val Ile Trp Tyr Lys
165     170     175

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## Rule 29

The human body and its elements

(3)

The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application

**= diagnostic ???**

6. A method to determine whether a subject is or is not (such as, for example, still is, or is no longer) in need of a therapy to treat hypervolemia or hypovolemia, comprising:

(i) measuring the quantity of MCAM in a sample from the subject, wherein the sample is selected from blood, serum or plasma;

**= IN VITRO**

(ii) comparing the quantity of MCAM measured in (i) with a reference value of the quantity of MCAM, said reference value representing a known diagnosis, prediction and/or prognosis of hypervolemia or hypovolemia or euvolemia;

(iii) finding a deviation or no deviation of the quantity of MCAM measured in (i) from said reference value;

(iv) inferring from said finding the presence or absence of a need for a therapy to treat hypervolemia or hypovolemia.

**ACTION !**

**Δ CHANGE**

**= RESULT**

As technology advances and matures, computer-implemented inventions are used increasingly in all fields of technology.



In many cases the innovative part of a new product or process may well lie in the method underlying a computer program and/or its computational implementation.

SOFTWARE

MACHINE



MICROFLUIDIC ASSAY PLATE



(Article 52(2)(c) and (3) EPC).

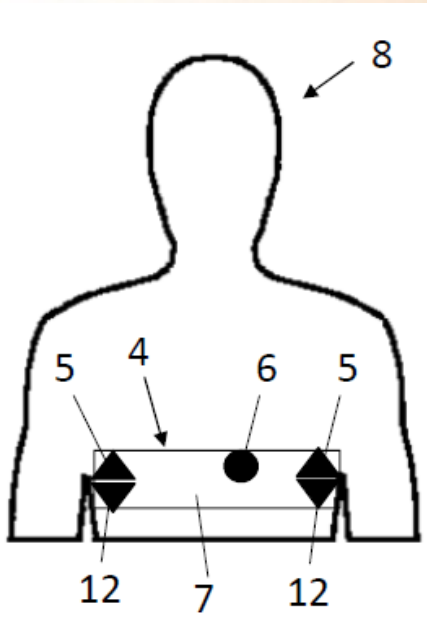
*(2)The following in particular shall not be regarded as inventions within the meaning of paragraph 1:*

*(c) [...] and programs for computers;*

***Under the EPC, a computer program claimed "as such" is not a patentable invention***

Patents are not granted merely for program listings. Program listings as such are protected by copyright.

***For a patent to be granted for a computer-implemented invention, a technical problem has to be solved in a novel and non-obvious manner.***



## ***Arterial blood pressure measurement***

1. A method for measuring and determining a pulse arrival time (PAT) value of a user using a sensor device (4) comprising a photoplethysmographic (PPG) multichannel sensor (9) formed from a plurality of PPG sensor channels and being adapted to measure a set of PPG signals, each PPG signal being measured by one of the PPG sensor channels when the multichannel PPG sensor (9) is in contact with the user; comprising:
  - **measuring** said set of PPG signals;
  - **extracting** a plurality of features from each of the measured PPG signals;
  - **selecting** a subset from the set of PPG signals based on the extracted features; and
  - **processing** the selected subset of PPG signals to determine the PAT value





## Claim

**Computer carrier**  
comprising **program code portions** to be executed by a signal processing device in order to carry out the method of one of the claims 1 to 15 when said program is executed by said signal processing device.

**3D printing  
Additive manufacturing (AM)**

*Product Claim*

A syringe, characterized by a piston with flat wall joined with ribs

*File Claim*

A **computer storage medium** containing **executable data** by a 3D printing system to **generate the impression** of a piston for a syringe, with flat wall joined with ribs



?

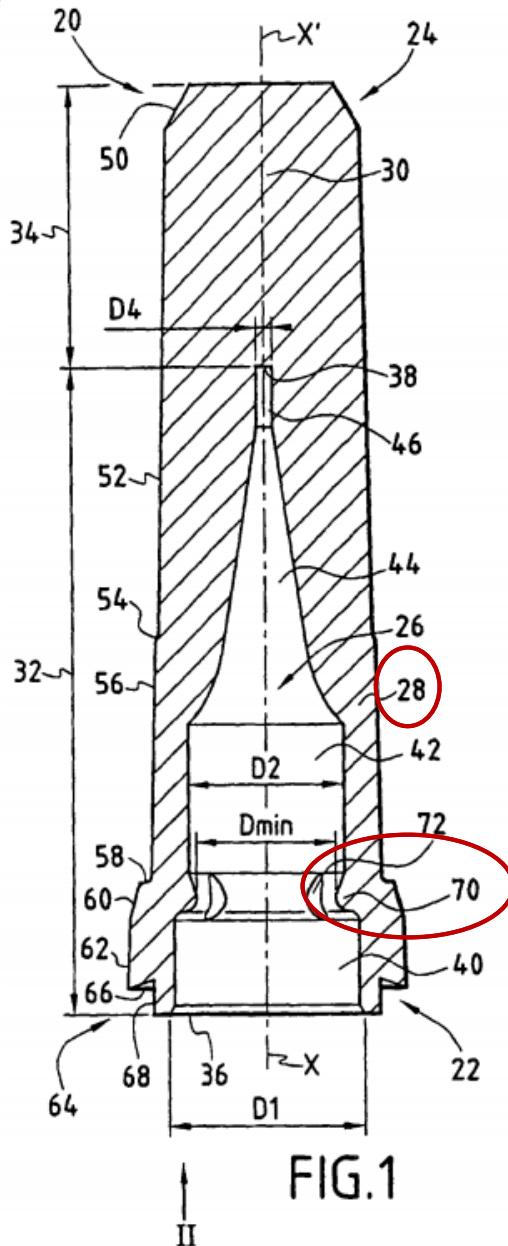


## Article 84 EPC

### Claims

*The claims shall define the matter for which protection is sought. They shall be **clear** and concise and be supported by the description.*

*A.100 EPC Grounds for opposition  
(b) the European patent does not disclose the invention in a manner sufficiently **clear** and complete for it to be carried out by a person skilled in the art;*



Claim 1. Device for protecting a syringe needle comprising an elastic needle cap (20) [...] being formed by a lateral wall (28) [...] defining an inner housing (26) adapted to receive the distal part (104) of the body (102) of a needle syringe (100), and by an end wall (30) [...] characterised in that said **lateral wall (28) is further provided with an annular bead (70)** disposed in said housing (26) between said first and second portions (40, 42) of said housing (26), at least one slot (72) extending longitudinally over said annular bead (70).

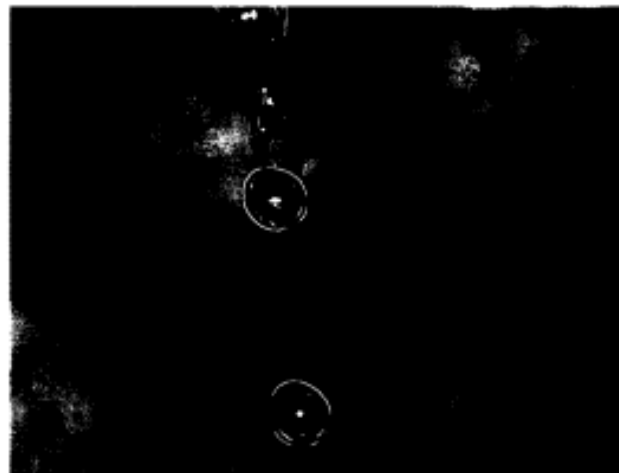
2. said bead (70) presents in longitudinal cross-section the **shape of a half drop of water** of which **the widest part faces the proximal end (22) of the cap (20)**.

**Opposition !**

## Opponent's position

### « shape of a half drop of water »

While the European Patent seems to assume that a drop of water always has a form commonly known as 'teardrop' (♠), it is clear that drops of water in their usual state, i.e. falling under the influence of gravity, are essentially spherical (●). Below is reproduced a picture from the Wikipedia showing two drops of water falling from an icicle.



drop of water

= sphere ○

-> Use of **prior art** with beads having a **shape of a portion of sphere**

## Patentee's position

Images from Wikipedia « drop »  
can have different shapes, with a  
**majority of « tear drop shape »**  
or « **pear shape** » as described



Goutte d'eau art print, poster  
by ...  
297 x 400 pixels - 13 ko - jpg  
20six.fr



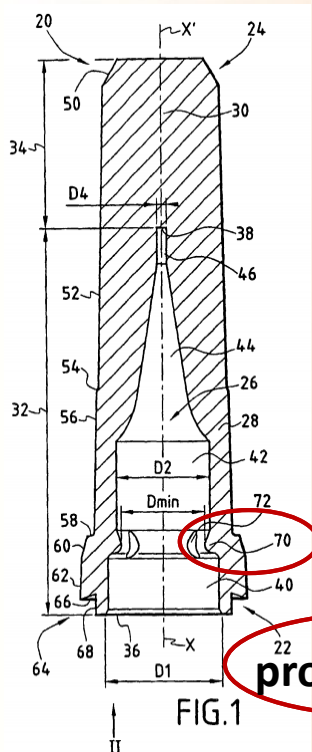
rojet Goutte d'eau, Goutte de  
vie ...

## Position of Opposition Division

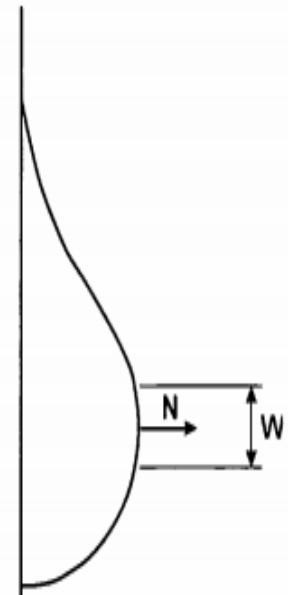
-> **prior art** with  
Spherical Shape  
is not relevant

## Opponent's position

2. said bead (70) presents in longitudinal cross-section the **shape of a half drop of water** of which  
**« the widest part faces the proximal end (22) of the cap (20) »**



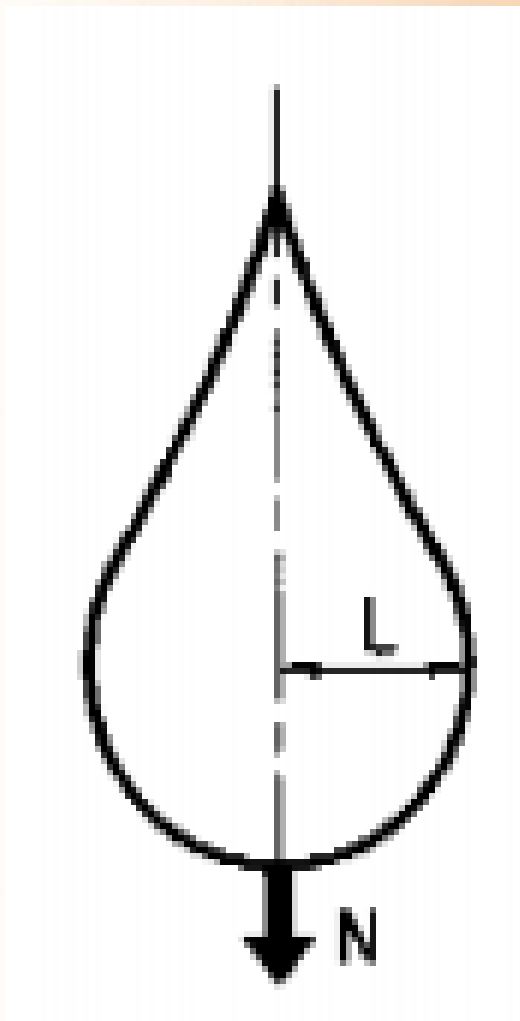
With reference to the figure shown on the right, the widest part of the half drop of water (as disclosed in the drawings of the European Patent) is the part indicated by "W". For determining the direction this part faces, the only reasonable method is determining the surface normal which, in the figure, is indicated by arrow "N". Accordingly, the widest part of the half drop of water cannot face either the proximal nor the distal end of the cap, and the skilled person thus is not able to carry out the teaching of claim 2.



-> UNCLEAR

-> Skilled person cannot carry out the invention

### Patentee's position



**widest part of the « tear drop »**  
is the **bottom part** having the  
shape of a half circle , with the  
normal direction **N pointing**  
**down**

### Position of Opposition Division

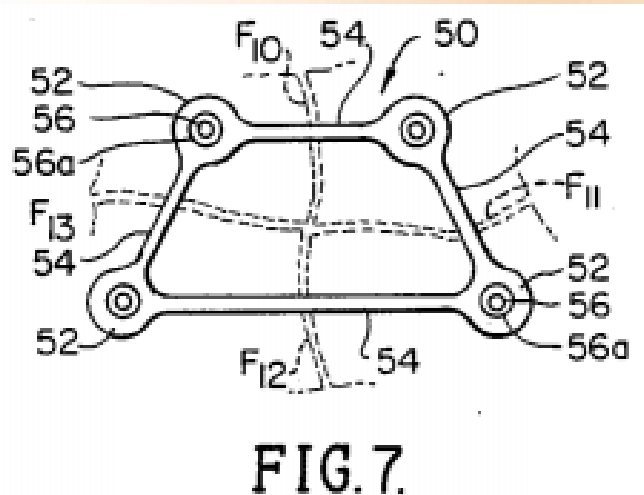
This expression is **CLEAR !**

**Opposition rejected !**

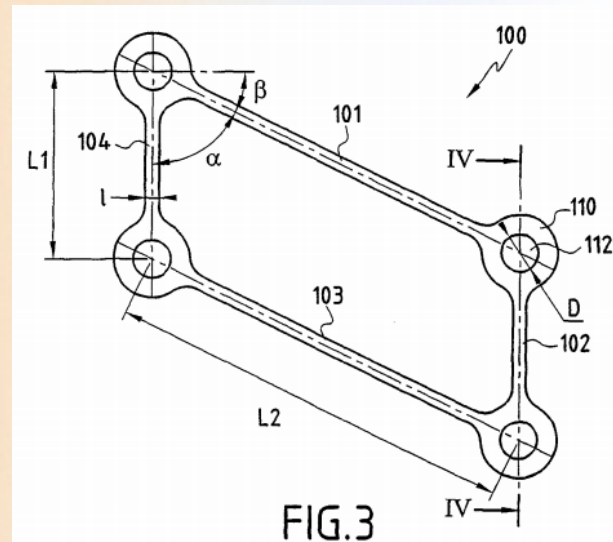


**Is that possible to get a patent  
for simplification of a known  
Construction ?**

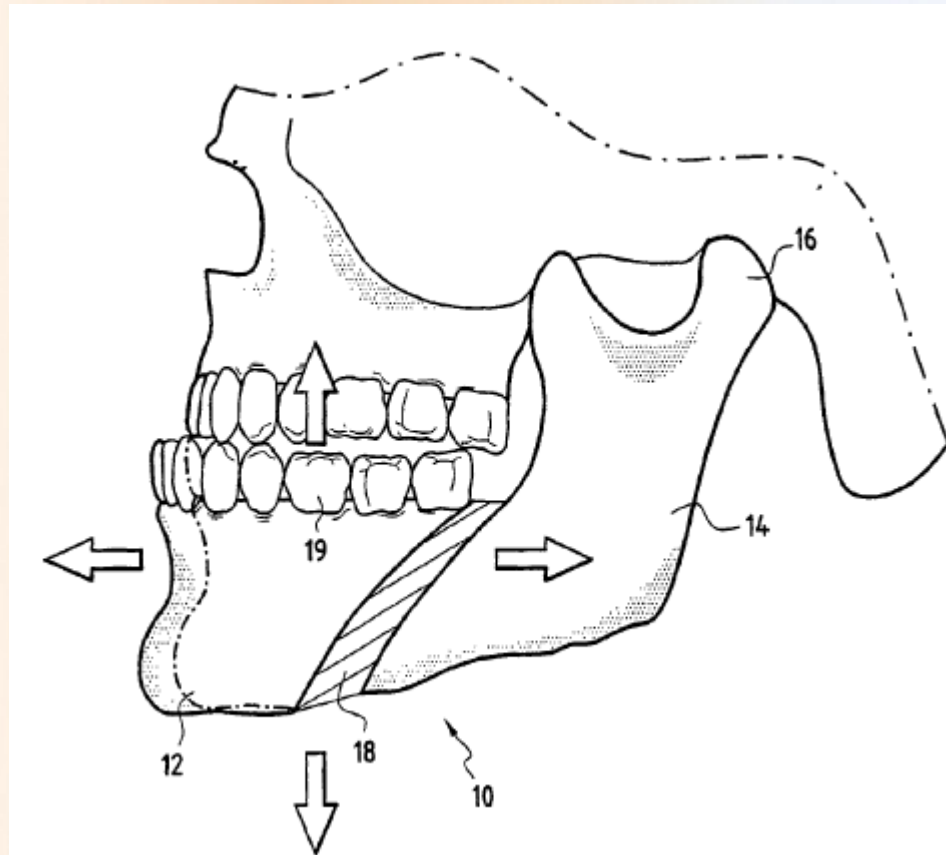
## Osteosynthesis plate



PRIOR ART = D1



INVENTION



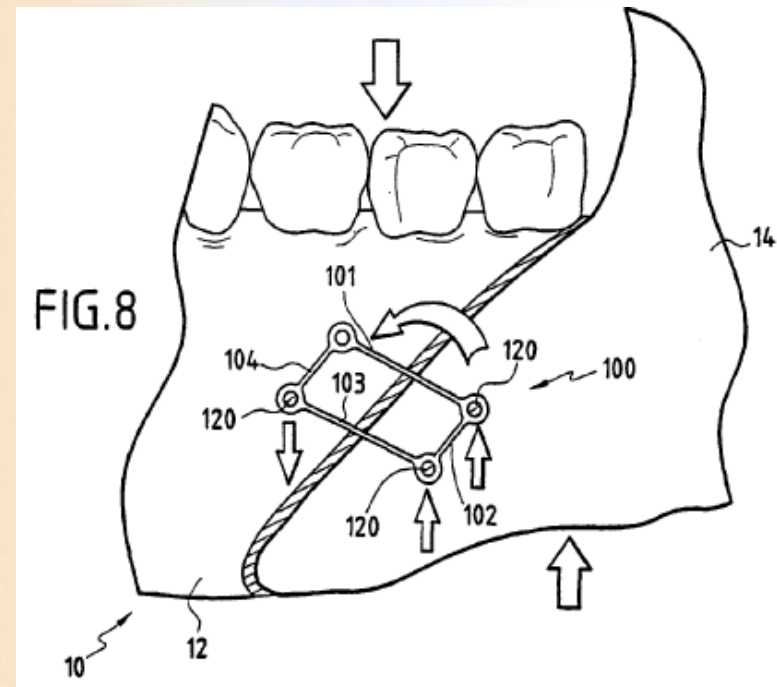
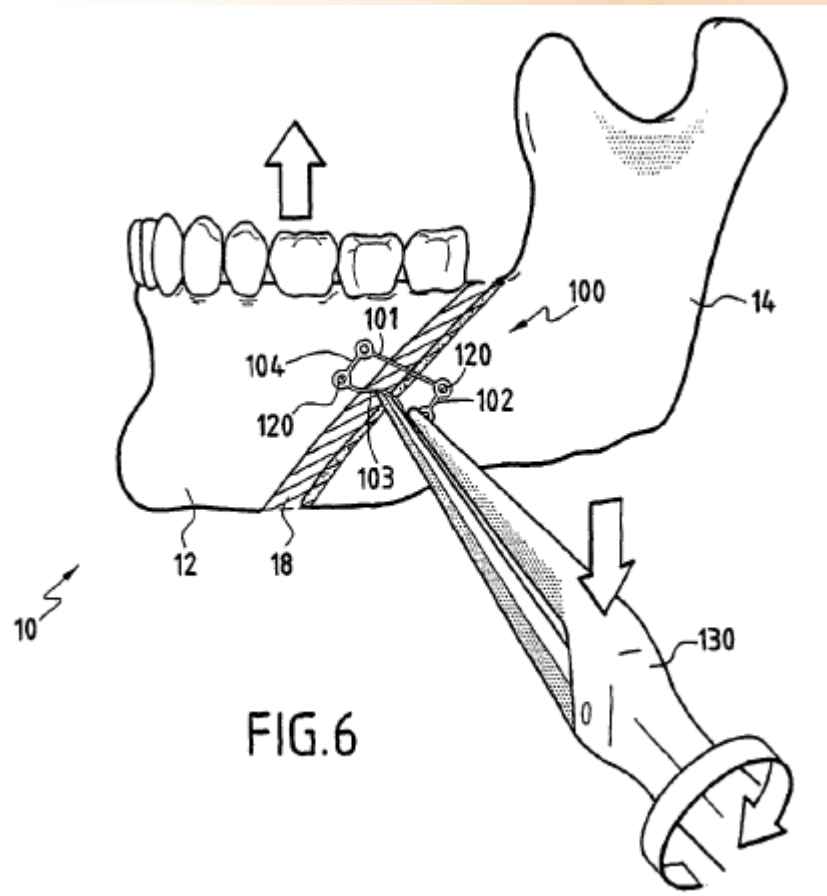
**mandibular osteotomy = mandibular displacement  
orthognathic surgery  
(also known as corrective jaw surgery)**

## Invention = New surgery technique

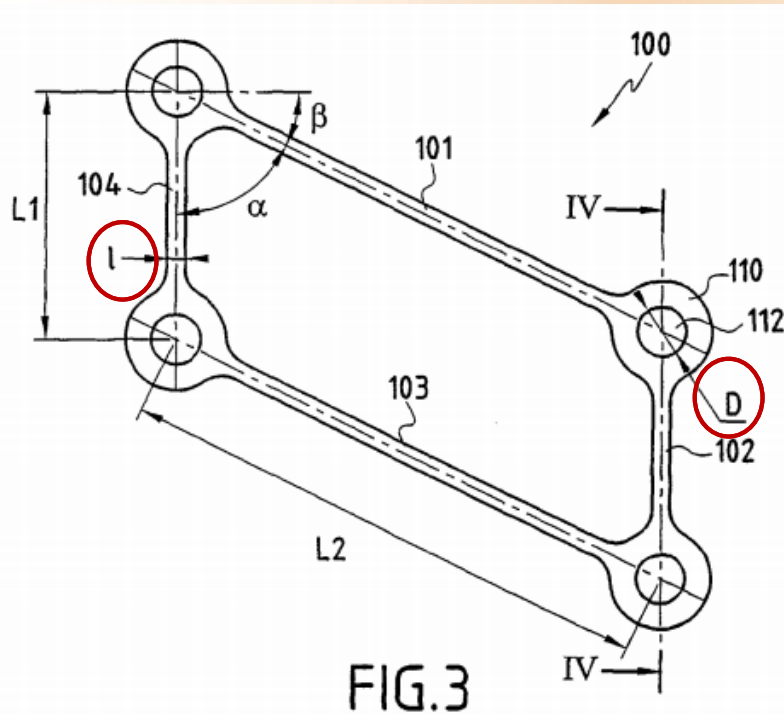


Article 53 EPC  
*European patents shall not be granted in respect of:*  
*(c) methods for treatment of the human or animal body by surgery*

→ Not possible to protect the surgery method



Adjustment of the height of the lower jaw in a parallel manner to the cut line



What's specific with the PLATE ?

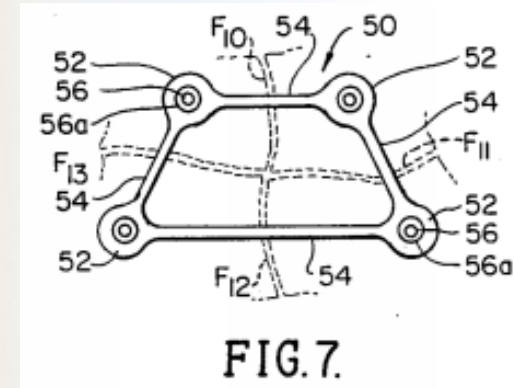
- shape= parallelogramm
- Two long branches 101, 103
- Two short branches 102, 104
- $50^{\circ} < \text{Angle } \alpha < 80^{\circ}$
- At least one adjustment branch  
Width  $l < \text{diameter } D$  of the bores -> to be easily deformed when three angles of the plate are screwed

-> to be easily deformed when three angles of the plate are screwed

## Examiner's position

### *Differences vis-à-vis D1*

- Plate = parallelogramm
- At least one adjustment branch  
Width  $l < \text{diameter } D$  of the bores  $\rightarrow$



### *Objections*

A 83 EPC : Disclosure of the invention

A 84 EPC : Clarity

claim 1 lack essential technical features to obtain the technical effect (to adjust the relative position of two bones fragments in a parallel manner to the cutting line)

A parallelogramm is one possibility that the skilled man could choose among several obvious possibilities

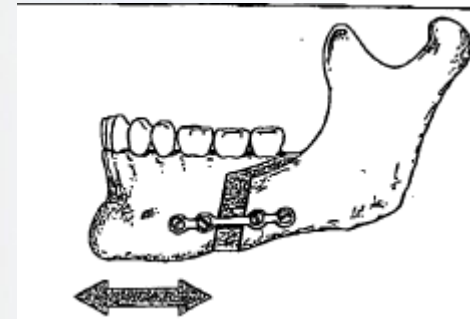
## Applicant's position

## Prior art surgical technique

B. Négrier  
D. Deffrennes  
E. Hadjean  
M. Vaugeois

### Ostéotomie sagittale de la mandibule

L'ostéotomie sagittale du ramus est associée aux noms de Trauner-Obwegeser (1955) et de Dal-Pont (1959).



*Difficulties to adapt the position of the fixing points prior to the deformation of the plate so that the right relative position of the bones is obtained*

## New surgical technique

*The parallelogram shape combined with the easy deformation of the branch(es) allow to obtain a good in situ adjustment by deforming in several step the already partially fixed plate*

# Grant of the patent !

# THE END

## PLEASE ASK YOUR QUESTIONS !

Thank you for your attention !

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