

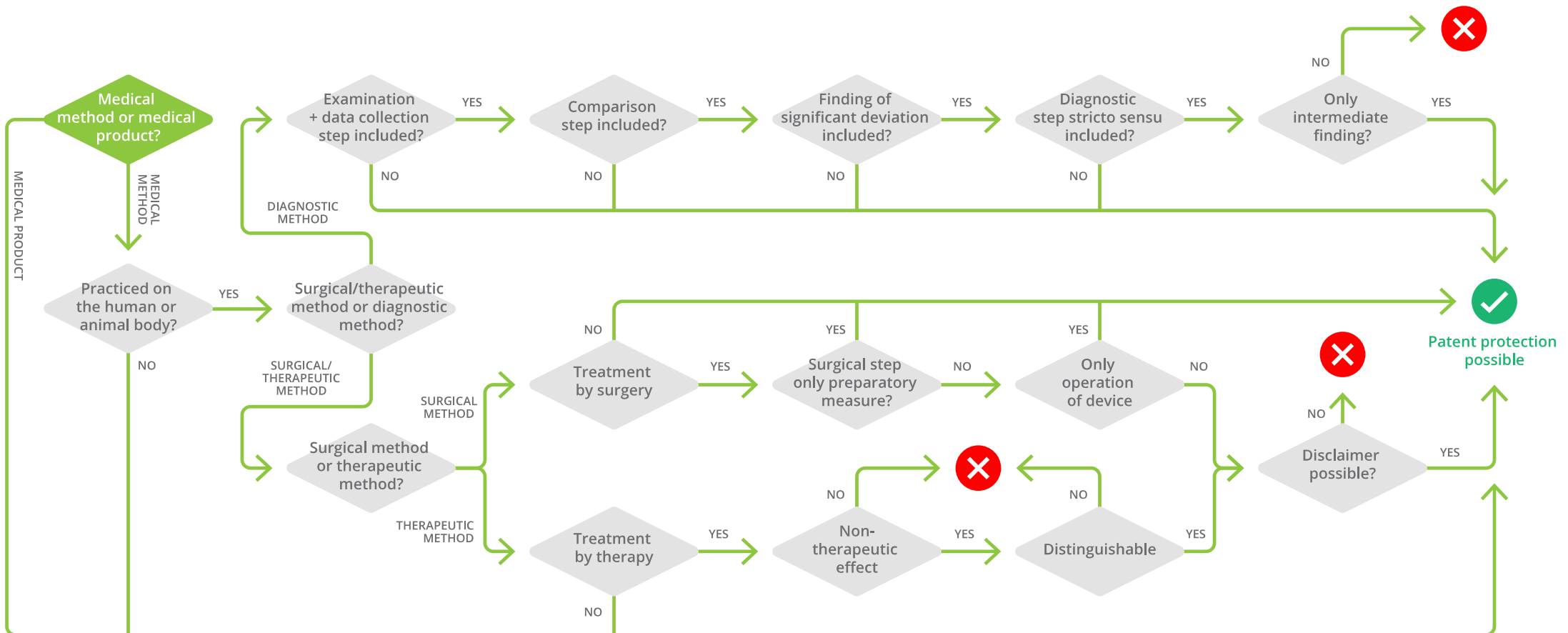
BERGGREN



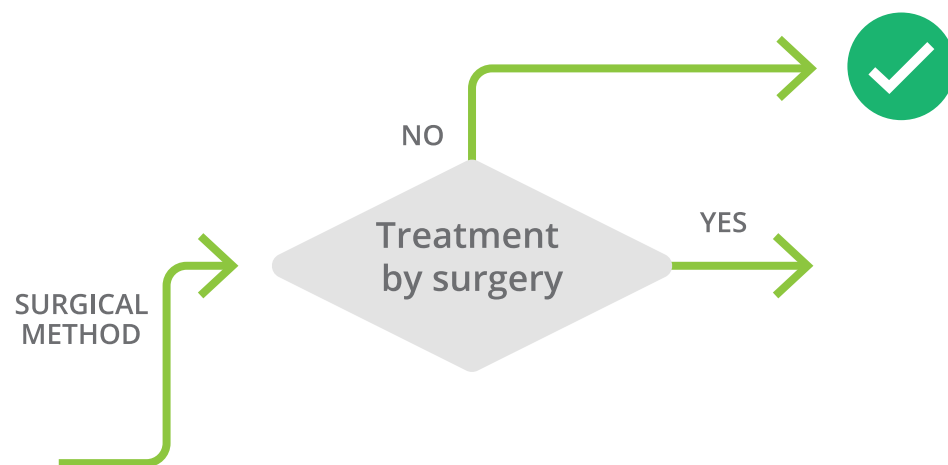
Is my medical invention patentable?

Part 5 – Treatment by surgery

Overview



Treatment by surgery



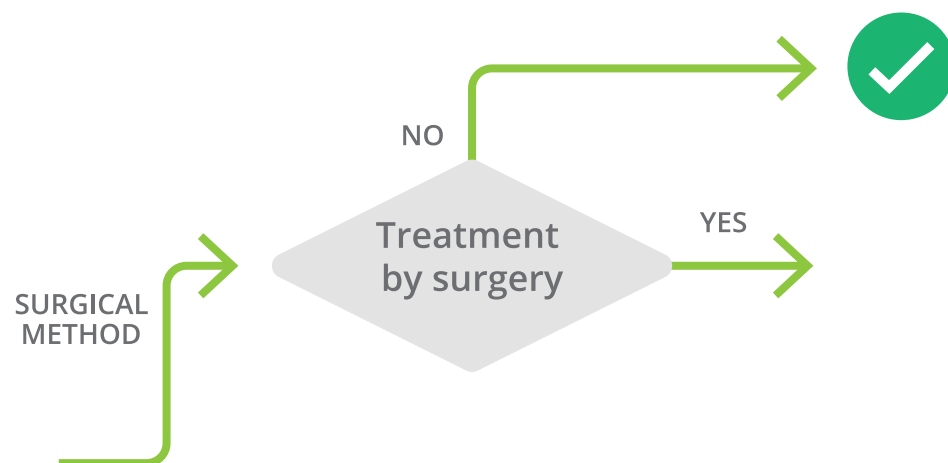
- **One** (or more) surgical **step(s)**
→ **Excluded** from patent protection¹
- **Surgical step** does **not** have to have **curative** or therapeutic purpose²
- Surgical step may be **implicitly covered**³

1 G 1/07, Reasons 3.2.5

2 G 1/07, Reasons 3.3.10

3 G 1/07, Reasons 4.3.1;
T 923/08; T 2102/12; T 1631/17

Surgical step



- **Substantial physical intervention** on the body that entails a **substantial health risk**²
- **Not** necessary that step is **invasive** or that tissue is penetrated²
- **Not relevant who** executes the surgical step³
 - whether method/step can be delegated at best indicator⁴

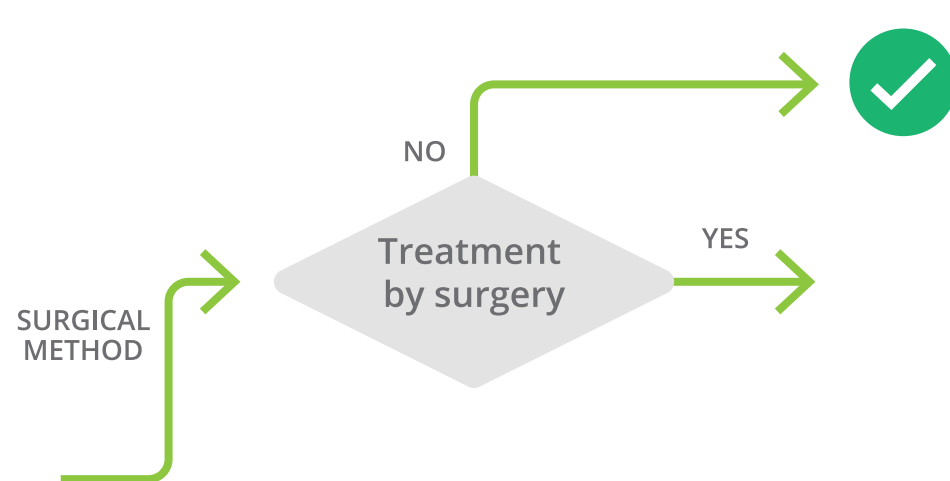
1 G 1/07, Headnote 1
2 T 5/04

3 G 1/07, Reasons 3.4.1;
G 1/04, Reasons 6.3

4 T 467/18, Reasons 3.8

Substantial health risk

Assessment via:



- **Risk matrix¹**
 - Statistical health risk scores
- **Abstract risk criterion²**
 - Substantial health risk when **beyond side effects** associated with treatments like tattooing, piercing, hair removal by optical radiation, skin micro abrasion

1 T 663/02

2 T 1695/07;
G 1/07, Reasons 3.4.2.2

Some examples

- **Substantial health risk:**
 - Venipuncture and the **extraction of blood**¹
 - Continuous **removal of blood**, flowing through extracorporeal circuit and re-delivery (haemodialysis / apheresis)²
- **No substantial health risk:**
 - **Injecting** magnetic resonance contrast agent **into a vein**³
 - **Retraction of a sulcus**⁴
 - **Expansion** of elastomeric material **within the sulcus**⁵

1 T 1075/06

3 T 663/02

5 T 2699/17

2 T 1695/07; T 434/15; T 1927/16 4 T 467/18; Reasons 3.6 – 3.7

Case law example: Instrument alignment (T 2438/11)

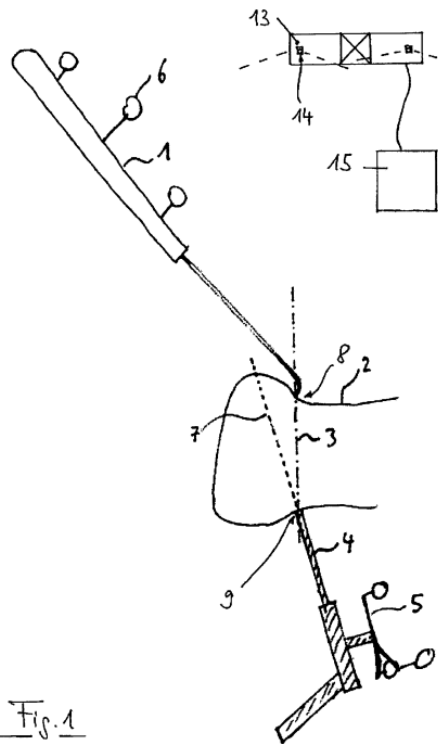


Fig. 1

Claim 1: Method of aligning an instrument, in which a medical instrument to be aligned [...] is being aligned with the target point (8) by means of a medical navigation (15) connected with the tracking system.

- Method may be practiced with medical instruments like bone drills.
 - Dissecting the bone and drilling the bone are **preparatory and subsequent** surgical steps.
- **Alignment method not a surgical method?**

BUT:

- According to the description the **aligning** of the instrument **at the dissected bone** may be executed **while the instrument is working**.
- **Significant physical intervention** on the body that entails a **significant health risk**.
- **Excluded** from patent protection



Sebastian Greding

European and German Patent Attorney

European Patent Litigator

I help clients to choose the best IP strategy based on the actual invention as well as based on the respective business case and their overall business strategy.

Berggren, Munich

 sebastian.greding@berggrengroup.de

 www.berggren.eu