The required medical expertise and the health risk involved may not be the only criteria which may be used to determine that a claimed method actually is a "treatment by surgery" within the meaning of Art. 53(c) EPC. It appears that what is to be understood by "surgery" in the medical sense is to a large extent a matter of convention. Thus, in order to be surgical, it is not necessary that the intervention be invasive or that tissues be penetrated (T 5/04). The scope of what is surgery may change with time and with new technical developments emerging, as was already acknowledged in decision T 182/90.

In <u>G 1/07</u>, with regard to the facts of the case, the Enlarged Board decided that a claimed imaging method, in which, when carried out, maintaining the life and health of the subject is important and which comprises or encompasses an invasive step representing a substantial physical intervention on the body which requires professional medical expertise to be carried out and which entails a substantial health risk even when carried out with the required professional care and expertise, is excluded from patentability as a method for treatment of the human or animal body by surgery pursuant to <u>Art. 53(c) EPC</u>.

4.4.4 "Treatment by surgery" in the case law since G 1/07

a) Surgical nature of a method step

In **T 992/03** of 4 November 2010, <sup>129</sup>Xe gas was used as part of the claimed method. The board referred to **G 1/07** according to which "there is an exclusion from patentability as a surgical method only if the health risk is associated with the mode of administration and not solely with the agent as such" and any anaesthetic effect of the <sup>129</sup>Xe gas thus did not fall under the exclusion.

b) Assessment of "substantial health risks"

In <u>T 663/02</u> the board held that the step of "injecting the magnetic resonance contrast agent into a vein remote from the artery" may be considered as representing a minor routine intervention which did not imply a substantial health risk when carried out with the required care and skill. Such acts would be ruled out from the scope of the application of the exclusion clause pursuant to <u>Art. 53(c) EPC</u> following the narrow understanding advocated by the Enlarged Board of Appeal (<u>G 1/04</u> and <u>G 1/07</u>). A possible way of assessing health risks is to use a risk matrix permitting the levels of likelihood and health impact of a complication of a medical act with regard to a large number of patients to be combined, so as to obtain statistical health risk scores which may be used to decide what action should be taken.

However, in <u>T 1075/06</u> the board held that venipuncture of blood donors and the extraction of blood from a donor's body represent substantial physical interventions on the body which require professional medical expertise to be carried out and which entail a substantial health risk even when carried out with the required professional care and expertise. A method claim comprising steps encompassing such procedures is a method for treatment of the human body by surgery.