

Similarly, in T.1695/07, the board held that a blood manipulation process involving the continuous removal of blood from a patient, its subsequent flowing through a circulating line of an extracorporeal circuit and its re-delivery to the patient was a method of treatment of the human body by surgery. It stated that even when the process was carried out with the required medical professional care and expertise, it involved "substantial health risks" for the patient. A health risk was considered to qualify as "substantial" whenever it went beyond the side effects associated with treatments such as tattooing, piercing, hair removal by optical radiation, micro abrasion of the skin as mentioned in G.1/07. A factual analysis of absolute or relative risks and their likelihood of occurrence based on objective evidence was hardly feasible and should therefore not be required.

In T.2699/17 the application related to the guided expansion of an elastomeric material within the sulcus of a tooth. In this way, the gingiva was retracted from the tooth, such that an appropriate impression of the tooth could be obtained, which was then used in the manufacture of the crown restoration. The criteria as defined in G.1/07 were applied and the board found that minor injury of the epithelium could occur. It then had to examine whether the method qualified as "substantial physical intervention on the body", i.e. whether the health risk was a substantial health risk within the meaning of G.1/07. For that evaluation, different approaches had been suggested in the case law, namely, the 'risk matrix' in decision T.663/02 and a 'more abstract risk criterion' in decision T.1695/07. The board followed the latter approach, which was limited to the question "Is a certain health risk present?" and "Is it substantial?" The board held that the risks here were at a level equal to those present in the methods which G.1/07 considered not to involve a substantial health risk (see also T.467/18).

In T.434/15 the inventions concerned apheresis, a method in which blood was removed from a person, passed through an apparatus for separating and collecting a particular constituent of the blood (in the present case, stem/progenitor cells) and re-transfused without the collected constituent. The fact that a certain method was routine for a highly specialised centre could not, according to the board, automatically lead to the conclusion that such a method would generally be a safe and routine technique. Apheresis was held to be a method using invasive techniques that allowed for extra corporeal manipulation of an organ of the human body. There were considerable health risks involved. Furthermore, apheresis could not be considered to be a generally safe, simple, routine procedure. Consequently, apheresis had to be seen as a method of surgery within the meaning of Art. 53(c) EPC.

c) Surgical step part of claimed method or simply a preparatory measure?

The boards have had to consider whether particular surgical steps form part of the claimed method or are simply preparatory measures which cannot be deemed such a part.

In T.992/03 of 4 November 2010, methods were claimed for MR imaging the pulmonary and/or cardiac vasculature of a subject, using dissolved-phase polarised ¹²⁹Xe gas. The board stated that delivering polarised ¹²⁹Xe gas to the subject and initialising the MR system were preparatory steps which, however, did not form part of the contribution of the invention to the art. The method claims thus did not comprise "an invasive step