SURGICAL STEPS IN EUROPEAN PATENT CLAIMS

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According to Article 53(c) of the European Patent Convention (EPC), European patents shall not be granted in respect of methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body.

Many applicants attempting to claim new surgical devices avoid including surgical steps in claims to evade Art 53(c) EPC. Nevertheless a surgical device often needs to be described in relation to the human body, its use and by means of functional terms. Case law on this topic is extensive but still developing, because applicants continue to relate to and, if appropriate, work around it.

In case G1/04, surgery in a diagnostic method included any physical intervention in which maintaining the life, or health, of a subject was of paramount importance. This decision was followed by case G1/07, which indicated that the exclusion from patentability should apply only to methods in respect of which it is justified on grounds of public health, the protection of patients and the freedom of the medical profession to apply the treatment of choice to its patients. G1/07 states that "any definition of the term treatment by surgery must cover the kind of interventions which represent the core of the medical profession's activities".

T1695/07 concerns a method of measuring arterio-venous shunt blood flow during haemodialysis to simplify the withdrawal of blood from a location close to the arterial side of the shunt and the return of the purified blood downstream of the withdrawal site. Following G1/07 the board took the view it cannot be considered as a "minor intervention" being performed on "uncritical parts of the body" when an artery and a vein are put together through anastomosis, to bypass the capillaries, and when the procedure is not performed in a "non-medical, commercial environment".

When blood flows through the shunt and the organs of the human body it performs functions essential to the patient's health. The Board of Appeal found that such a method involves "substantial health risks" for the patient, and that a health risk is considered to qualify as "substantial" whenever it goes beyond the side-effects associated with treatments such as tattooing, piercing, hair removal by optical radiation and micro-abrasion. The board made it clear that "substantial health risks" did not require a factual risk analysis based on objective evidence.

In this respect T1695/07 was consistent with T1075/06 where steps encompassing venipuncture of blood donors and the extraction of blood from a donor's body were deemed to represent substantial physical interventions on the body. Performing the steps required professional medical expertise and entailed a substantial health risk even when carried out with the required professional care and expertise. A method claim comprising the step of returning processed blood, depleted of some of its components and charged with an anticoagulant, to a donor is a method for treatment of the human body by therapy which is excluded from patentability under Article 53(c) EPC.

"THE OPPOSITION DIVISION HAD DEEMED THAT SUCH A METHOD WAS DIRECTED TO A DIAGNOSTIC METHOD INVOLVING SURGICAL STEPS, AND THE PROPRIETOR APPEALED AGAINST THE DECISION."

T0663/02 concerns a European patent for a method for magnetic resonance imaging of arteries in which a magnetic resonance contrast agent is injected intravenously. The Opposition Division had deemed that such a method was directed to a diagnostic method involving surgical steps and the proprietor appealed the decision. The Technical Board of Appeal waited for G1/04 and G2/07 before dealing with the present case; following those, the patent was maintained as granted.

In its reasoning the board notes that the method did not relate to a diagnostic method. The main claim did not "include the deductive medical or veterinary decision phase, ie, the *diagnosis stricto sensu*. Rather, it only includes the preceding steps of gathering information which are constitutive for making the diagnosis ('monitoring ..., detecting ..., generating ..., collecting ..., constructing ...'), and the specific interactions with the human or animal body ('injecting ...') which occur when carrying out said preceding steps".

In line with the narrow understanding advocated by G1/04 and G1/07 the board found that the fact the physician can delegate the task to a qualified paramedical professional indicates that such an injection represents a minor routine intervention which does not imply a substantial health risk when carried out with the required care and skill. Thus Art 53(c) did not exclude the method for this reason either.

T0663/02 suggested assessing health risks by using a "risk matrix" that combines the levels of likelihood and health impact of a complication of a medical act with regard to a large number of patients, so as to obtain statistical health risk scores which may be used to decide what action should be taken. It will be interesting to see whether the risk matrix gains ground. ■

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