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Second medical use claims to medical devices

A decision (T1758/15) from the EPO Boards of Appeal helps to clarify the requirements for second medical use claims to medical devices under Article 54(5) EPC

In Europe, medical device inventions can fall into a difficult area of patent law; particularly where the invention lies chiefly in the way the device is used in a medical method, rather than in structural features of the device itself. This is because claims to medical device inventions need to avoid the treacherous waters of Article 53(c) EPC excluding methods of medical treatment from patentability, but may struggle to reach the safe harbour of second medical use claims under Article 54(5) EPC (a legal fiction in compensation for the exclusion under Article 53(c) EPC where a known substance or composition is made novel by a new medical use). A recent decision from the EPO Boards of Appeal helps to clarify the requirements for second medical use claims to medical devices under Article 54(5) EPC.

The decision (T1758/15) concerned the patentability of a biocompatible, biodegradable filler material for use in a specific medical method. The method comprised injecting the filler into a space between a first tissue and second tissue of a patient (such as between the rectum and prostate), and treating the first tissue with radiation therapy, whereby the filler material physically separated the first and second tissue so that the second tissue was exposed to reduced radiation for fewer side effects.

The filler material (comprising collagen or hyaluronic acid) was already known in the art. It was also known to inject collagen into tissue (such as into the perineum for improving urinary incontinence). The specific medical method of using the filler in the invention appeared new and inventive, but claims to this method were refused as relating to a method of medical treatment on the human body excluded from patentability under Article 53(c) EPC.

Thus, the applicant tried to seek patentability of the filler material in the form of a second medical use claim under Article 54(5) EPC. This article provides a legal fiction that a known substance or composition (i.e. the filler material) can be rendered novel by a new medical use. Thus, the applicant submitted claims along the lines of “A biocompatible, biodegradable filler material for injection and for use in radiation treatment…”.

However, the Board of Appeal decided that the filler material was not eligible for protection under Article 54(5) EPC, meaning the claims lacked novelty over commercially available collagen and the patent was revoked. The Board’s reasoning in this regard provides a good overview for why medical device inventions can be caught between Articles 53(c) and 54(5) EPC, and thus fail to secure patent protection in Europe.

Article 54(5) EPC only applies to “substances or compositions”. The filler material (e.g. collagen or hyaluronic acid) is certainly a substance or composition in a broad sense. However, with a view to the legislator’s intention behind the wording of the EPC 2000, the Board reasoned that the “substance or composition” of Article 54(5) EPC must mean something more specific.

The Board did not provide an explicit definition of a “substance or composition” in the meaning of Article 54(5) EPC. However, the Board did note that an approach from previous case law may be helpful, where it was suggested to establish (a) the means by which the therapeutic effect is achieved and (b) whether that which achieves the therapeutic effect is a chemical entity or composition of chemical entities.

In the present case, the filler material achieves the technical effect of reducing radiation-treatment-induced side effects by a mechanical means, displacing sensitive tissue relative to the target tissue. This mechanical displacement is achieved by a three-dimensional accumulated mass of filler material, not as a property of the filler material as a chemical entity or composition of chemical entities. Although the filler material is made up of chemical molecules, which have some influence on the characteristics of the resulting mass (e.g. non-toxicity, biodegradability etc.), the effect is achieved by the macroscopic 3D form and position of the mass.

The Board reasoned that the therapeutic effects of the filler material, such as holding open a particular volume and distancing sensitive tissue, are effects of the 3D macroscopic structure, and are only indirectly attributable to the substance from which the 3D structure is built (a similar concept appears in an earlier decision, T0826/06, relating to the second medical use of a medical device, which states that “a technical effect may confer novelty on the use of a known product only if there is a causal link between the product and the "new" technical effect for which the use is claimed”).

The applicant tried to argue that the filler material had a radiation-reducing effect that could be attributed to its chemical properties. However, the Board could not find this effect disclosed in the application and the applicant’s argument was dismissed.

The Board therefore concluded that the filler material did not have an “active principle” (i.e. takes an active role) with respect to the surgical method of its implantation, but was rather the passive object thereof. And, even if a potential active involvement was present, this would be an effect of the accumulated filler mass, not of the particular filler material (i.e. chemical entity).

In contrast, as an illustrative example of a substance or composition that the Board thought did have an active principle in the context of a surgical method, the Board referred to earlier case T0826/06, relating to a dye used for selectively staining the outer surface of the eye lens in cataract surgery. In this case, the Board concluded that the dye was (a) the means by which the selective staining facilitating the surgery was achieved, and (b) a chemical, thus qualifying as a substance or composition in the sense of what is now Article 54(5) EPC (in T0826/06, a Swiss-type claim in the fifth auxiliary request was found novel, but was later rejected under different grounds for lack of inventive step).

Also interestingly, the Board confirmed that Article 54(5) EPC can be applied to substances or compositions in any specific method of treatment of the human or animal body by surgery, whether or not the surgery or use of the substance or composition therein has a therapeutic effect (following from reasoning in Enlarged Board of Appeal decision G01/07). This suggests that substances or compositions need to provide an “active” effect in the sense of the method in question, but are not limited to pharmacological activity as such.

In conclusion, second medical use claims under Article 54(5) EPC remain a difficult prospect for medical device inventions, which in many cases may struggle to identify a chemical entity or composition of chemical entities to which an active effect can be directly attributed. However, there do seem to be some medical devices where second medical use claims might be available, such as dyes for use in surgery. Other examples might perhaps include bioactive materials, radioactive isotopes, bone cements, and ionised or charged particles.

A link to the full decision in T1758/15 can be found here.

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