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Second medical use claims for devices – an uneven playing field?

European patent law offers extra protection for pharmaceuticals that is not available for medical devices. Second medical use claims for pharmaceuticals are routinely accepted in Europe, whereas the same style of claim is generally not permissible for medical devices. Recent case law has seen a shift towards rewarding new uses for existing medical devices, but achieving such protection requires care during prosecution.

Novel and inventive methods of treatment involving a medical device or a pharmaceutical cannot be patented in Europe due to a statutory exclusion, unlike in the US. Some compensation is provided through the granting of second medical use claims, which protect the product only when it is intended for use in an excluded method of treatment. However, there is an inconsistency between the way European law treats medical devices and pharmaceuticals. Obtaining second medical use claims for medical devices is challenging in Europe, whereas the same style of claim is generally permissible for pharmaceuticals.

This uneven playing field was set down when the EPC was drafted, and recent cases have confirmed that it is challenging to get protection for new and inventive methods of using a medical device. This inconsistency can cause significant commercial problems where the device itself is not patentable. Thankfully, there are some routes for gaining a degree of protection for new methods involving a known medical device at the EPO.

The origin of the inconsistency: Articles 53(c) and 54(4) and (5) EPC

The distinction between second medical use claims for pharmaceuticals and medical devices originates from the inconsistency between the broad exclusion in Article 53(c) EPC and the relatively narrow range of second medical use claims permitted by Article 54(4) & (5) EPC.

Article 53(c) EPC states that:

> "European patents shall not be granted in respect of:
>
> (c) methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods." (emphasis added)

As a consequence of the use of the expression "in particular", Article 53(c) EPC indicates that the term "products" is not limited to "substances" or "compositions" and so methods of using medical devices can also be excluded.

Protection can be obtained for medicinal products subject to the usual patentability requirements. Therefore a new pharmaceutical or a new medical device would not be excluded from patentability on the basis of this article. The problem comes where the pharmaceutical or medical device is not new and instead the invention lies in the way it is used.

Articles 54(4) and (5) EPC provide an exemption to the normal laws of novelty for a substance or composition intended for medical uses:

> "(4) Paragraphs 2 and 3 shall not exclude the patentability of any substance or composition comprised in the state of the art, for use in a method referred to in Article 53(c), provided that its use for any such method is not comprised in the state of the art.

> (5) Paragraphs 2 and 3 shall not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art." (emphasis added)

It is here that the inconsistency appears. Article 53(c) EPC explicitly excludes any therapeutic use of a product (which includes medical devices), whereas Articles 54(4) and (5) EPC only apply to "substances" and "compositions". The EPO's Boards of Appeal have held that this inconsistency means that the novelty generating provisions of Article 54(4) and (5) EPC cannot be used for new medical uses of known products which are not substances or compositions (e.g. medical devices). Therefore, where a device is known from the prior art, a second medical use claim directed towards that device for use in a novel and inventive method of treatment would be held to lack novelty over the known device. This is in stark contrast to the situation for a known pharmaceutical, where a second medical use claim would be allowable for the compound when intended for use in a novel and inventive method of treatment.

What is a substance or composition?

In order to decide whether an invention can be protected by using a second medical use claim, it is necessary to first decide whether the invention can be classified as a "substance" or "composition". Several cases from the Boards of Appeal show that the terms "substance" and "composition" are considered narrowly. In decision T1069/11 the second medical use claim was directed towards a "stent for use in prevention of restenoses of a wall (3) of a blood vessel having atheromatous plaque". The stent was a finished product that did not include any active ingredient and so it was found not to qualify as a substance or composition by the Board. Likewise, in T1099/09, a "strip made from biocompatible material" for use in the treatment of female urinary incontinence was also found to be neither a "substance" nor a "composition".

Further interpretation of the meaning of "substance" or "composition" was provided in decision T2003/08. The Board stated that Articles 54(4) and (5) EPC should apply to claims which qualify as "chemical entities" or compositions of chemical entities. These chemical entities should provide the means by which a therapeutic effect is achieved. Thus, the claimed "use of a specific ligand for human immunoglobulin in the manufacture of a column having said ligand coupled thereto for the treatment of a patient suffering from dilated cardiomyopathy," was interpreted as a second medical use claim. The specific ligand, the means by which the therapeutic effect was achieved, was a chemical entity and therefore was to be considered to be a "substance" or "composition". The Board found that the "column" (a medical device) merely served as a carrier for the ligand and was not instrumental in achieving the therapeutic effect, but nonetheless allowed the second medical use claim in relation to the ligand for use with the column.

The requirement in T2003/08 for the therapeutic effect to be achieved via a "chemical entity" goes beyond the position of the Enlarged Board of Appeal in G5/83, which simply held that the "substance or composition" itself must have a therapeutic effect. In any case, a claim directed towards a new use of a known substance or composition together with a device, where the substance itself provides the therapeutic effect, could be permissibly formatted as a second medical use claim.

G2/08 increased the possibilities for protecting new medical uses involving a device

The Enlarged Board of Appeal decision G2/08 held that where it is already known to use a medicament to treat an illness, Article 54(5) EPC allows this medicament to be patented for use in a different type of treatment of the same illness. This decision confirmed that second medical use claims can be novel solely due to the presence of a new dosage regimen or a new mode of administration.

G2/08 opened up a whole new range of options for gaining protection for a method of using a medical device. While the second medical use claim must refer to a "substance" or "composition" – i.e. a chemical entity – the method can specify that the chemical entity is used in conjunction with a device. For example, claims directed towards a drug for use a method of treatment in which the drug was administered via a device can now be protected using Articles 54(4) and (5) EPC. Such a claim can be both novel and inventive solely by virtue of the reference to its use with the device. Therefore, careful claim drafting can provide a degree of protection for a drug intended specifically for use in the particular device.

Carpmaels & Ransford LLP have had some success in this area. For example, in EP2227257 the second medical use claim read:

> "A radionuclide brachytherapy source (RBS) for use in a method of irradiating a target of an eye in a patient, wherein said RBS is present in a cannula according to claim 1, the method comprising inserting said cannula into a potential space under a Tenon's capsule of the eye of the patient, the cannula having the RBS at a treatment position, whereby the RBS is positioned over the target, and the RBS irradiates the target".

Conclusion

Securing patent protection for a new therapeutic use of a known device is not straightforward at the EPO. Nonetheless, there are some options for obtaining protection for the new medical use of a known device where a substance or composition is used as a part of the therapeutic method.

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